

Exhibit 2



UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESAL PRICE)	MDL No. 1456
LITIGATION)	
_____)	CIVIL ACTION: 01-CV-12257-PBS
)	
THIS DOCUMENT RELATES TO)	Judge Patti B. Saris
01-CV-12257-PBS AND 01-CV-339)	
)	Chief Magistrate Judge Marianne B. Bowler
)	
)	[FILED UNDER SEAL PURSUANT TO
)	COURT ORDER]
_____)	

DECLARATION OF RAYMOND S. HARTMAN
IN SUPPORT OF PLAINTIFFS' CLAIMS OF LIABILITY
AND CALCULATION OF DAMAGES

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I. Introduction and Overview

1. My name is Raymond S. Hartman. I have previously presented my qualifications to this Court. In Attachment A, I attach my current curriculum vitae and a listing of testimony and/or appearances at deposition or trial. Attachment B is a listing of materials relied upon.

2. I have been asked by Counsel to determine, using standard economic methodologies and the data which are sufficient for implementing such methodologies, the aggregate overpayment for specified drugs during the Class Period due to the alleged wrongful conduct of Defendants. As a matter of economics, quantitative analysis and common pharmaceutical business practices, I conclude that aggregate Class-wide damages can be calculated accurately and reliably using standard formulaic methodologies. In Section II, I report the aggregate damages to the Class attributable to each of the five Track One Defendants. The balance of this declaration discusses the basis for the estimation of these aggregate damages and proceeds as follows:

- In Section III, I discuss how the August 16, 2005 *Memorandum and Order* of Judge Saris¹ shapes my analysis of causation, liability and estimation of aggregate Class-wide damages.
- In Section IV, I discuss my yardsticks and demonstrate how my formulaic methodology is implemented for each of the three Sub-Classes recognized by the Court.
- In Section V, I discuss why the use of average Class-wide measures of prices and reimbursement rates are appropriate for the demonstration of causation and liability and the calculation of aggregate damages.
- In Section VI, I address specific objections raised by Defendants' experts and mentioned by the Court; I demonstrate that these objections are without merit.
- In Section VII, I demonstrate that J-Codes do not require individual inquiry and do not interfere with the accurate calculation of aggregate damages.
- In Section VIII, I introduce and implement my yardstick methodology for the demonstration of causation and liability.

¹ *In re: Pharmaceutical Industry Average Wholesale Price Litigation, Memorandum and Order re: Motion for Class Certification*, United States District Court, District of Massachusetts, MDL No. 1456, Civil Action No. 01-12257 (hereafter *Memorandum and Order*).

- In Section IX, I implement my formulaic methodology to calculate aggregate Class-wide damages. It is important to note that the calculations have been conditioned by Defendants' responses to Plaintiffs' data requests. Where data have not been provided or have been provided incompletely, I have extrapolated, using standard economic methodologies, from those data that I have received to calculate total aggregate damages. To the extent that the data provided to me are incomplete, if I am asked by Counsel, I will supplement my Declaration as I receive more complete information from Defendants and am able to analyze that information.
- In Section X, I summarize the Declaration.

3. My conclusions, based on standard economic theory and practices, are the following:

- The methodology proposed in my September 3, 2004 Declaration in Support of Class Certification is appropriate for the demonstration of liability and the calculation of aggregate damages for each of the three Sub-Classes identified by the Court. I implement that methodology to determine causation and liability for all NDCs of all drugs alleged for the Track One Defendants. I find that the AWP's for most of the physician-administered drugs exceed the appropriate threshold for a finding of liability in this matter.
- For those drugs whose AWP's exceed the threshold levels for a finding of liability, I calculate the damages to the Sub-Classes identified by the Court using the methodologies put forward in my September 3, 2004 Declaration and refined in later Declarations. I find that the aggregate Class-wide damages are substantial.
- The use of average measures of actual and but-for reimbursement rates within my formulaic damage methodologies is appropriate for the calculation of aggregate damages. Issues of variation among Class members are manageable, and issues of allocation of aggregate damages to particular members or groups of members of each Sub-Class do not predominate at this stage of the litigation. Proper allocation can be implemented during the Claims Administration Phase, using standard methods.
- The use of J-Codes by commercial payors does not interfere with accurate calculation of aggregate Class-wide damages.

II. Summary of Estimated Class-Wide Damages

4. For each Track One Defendant, I calculate the ASPs and gather data on the AWP's required to determine causation and liability. Upon a finding of liability, I estimate damages to each of the Sub-Classes. A finding of liability draws upon a more refined implementation of the yardstick analysis already begun in my earlier Declarations. The aggregate Class-wide damages are substantial overall and for each Track One Defendant. The damages are summarized in Table 1.

Table 1.a: Summary of Damages (Nominal \$)

Company	Medicare Beneficiaries	Medicare Third-Party Payors		Non-Medicare, TPPs and Consumers	
	Massachusetts (Sub-Class 1)	National	Massachusetts (Sub-Class 2)	National	Massachusetts (Sub-Class 3)
AstraZeneca	\$35,802,381	\$179,011,907	\$4,731,827	\$270,529,238	\$7,150,907
Bristol Myers-Squibb	\$11,073,909	\$55,369,544	\$1,463,585	\$107,682,292	\$2,846,369
GlaxoSmithKline	\$7,680,758	\$38,403,792	\$1,015,129	\$369,418,857	\$9,764,859
Johnson & Johnson	\$36,956,579	\$184,782,896	\$4,884,372	\$165,001,084	\$4,361,479
Schering-Plough	\$38,450,573	\$192,252,864	\$5,081,826	\$32,585,296	\$861,328

Table 1.b: Summary of Damages with Pre-Judgment Interest (2005 \$)

Company	Medicare Beneficiaries	Medicare Third-Party Payors		Non-Medicare, TPPs and Consumers	
	Massachusetts (Sub-Class 1)	National	Massachusetts (Sub-Class 2)	National	Massachusetts (Sub-Class 3)
AstraZeneca	\$42,900,201	\$241,054,860	\$6,371,810	\$320,869,875	\$8,481,563
Bristol Myers-Squibb	\$13,456,089	\$76,486,931	\$2,021,781	\$134,180,816	\$3,546,805
GlaxoSmithKline	\$10,137,934	\$60,634,993	\$1,602,767	\$464,765,160	\$12,285,151
Johnson & Johnson	\$41,964,493	\$228,006,500	\$6,026,903	\$187,335,250	\$4,951,838
Schering-Plough	\$50,221,856	\$297,940,358	\$7,875,466	\$47,030,510	\$1,243,159

III. Identification and Analysis of Sub-Classes Recognized by Judge Saris

A. The Sub-Classes

5. I understand that Judge Saris has putatively certified the following end-payor Sub-Classes, subject to the following caveats:²

² *Memorandum and Order*, pp. 88 & 4.

a) **Sub-Class 1: Nationwide class of Medicare Part B beneficiaries**

“The motion to certify a nationwide class of Medicare Part B beneficiaries is deferred pending plaintiffs’ proposed amendment to add individual class representatives. I will then certify the nationwide class (except in those states where class actions are not authorized or notice was not given) if adequate individual class representatives are found.”

b) **Sub-Class 2: Massachusetts class of TPPs that provide Medigap-type supplemental insurance**

“The motion to certify a nationwide class of TPPs that pay MediGap-type supplemental insurance to cover Medicare co-payments is **DENIED**, but the Court will certify a statewide class under Mass. Gen. Laws ch. 93A.”

c) **Sub-Class 3: Massachusetts class of TPPs and consumers paying for physician-administered drugs outside of Medicare³**

“The motion to certify a nationwide class of TPPs and consumers paying for physician-administered drugs in the private context based on AWP is **DENIED**, but the Court will certify a statewide class for brand-name drugs and those generic drugs for which reimbursement was explicitly based on AWP, not MAC pricing.”

6. With respect to **Sub-Class 1**, Judge Saris has further opined (at p. 57) that it is appropriate to disaggregate the Sub-Class by Track One Manufacturer.

“With respect to Medicare Part B consumer patients making copayments, it is cost effective to focus the litigation in one forum, and one case will promote a uniformity of results appropriate for a nationwide reimbursement program. However, from a manageability point of view, it is appropriate to have subclasses of consumers for the drugs of each manufacturer group. Therefore, there will be five subclasses, one for each Track One group. The Court defers deciding whether to hold a separate trial with respect to each manufacturer group.”

I assume that the Judge had intended to extend this disaggregation to Sub-Classes 2 and 3.

7. The narrowing of the proposed classes to Medicare Part B and physician-administered drugs is relevant to my previously-submitted analysis in the following ways.

³ Should the Court certify Sub-Classes 2 and/or 3 on a national basis, I have calculated such damages as well. Table 1 reports these national damage calculations. Should the Court certify either of these Sub-Classes for a subset of states, I can easily extend these damage calculations to that subset of states.

- a) While the preponderance of these drugs is distributed to providers, for some NDCs of some Track One drugs, some units will be dispensed as self-administered orals to individuals in a non-Medicare setting. These units are excluded from the Class-wide impacts and damages, as are units dispensed in an in-patient hospital setting. The remaining units are those relevant to impact and damages for the certified Sub-Classes. Using invoice and non-invoice databases summarizing the units shipped, payments, chargebacks and rebates for the relevant customers and their classes of trade, I calculate ASPs as described in Section VIII.
- b) Not only is it necessary to calculate the units (and their ASPs) of each Track One drug reimbursed by the certified Sub-Classes, it is necessary to analyze the geographic nature of the reimbursements. Specifically, I must calculate those Medicare units the co-insurance for which is paid by Medicare beneficiaries in the United States as a whole (Sub-Class 1) but by TPPs for Massachusetts reimbursements only (Sub-Class 2). Likewise, for the non-Medicare physician-administered drugs (Sub-Class 3), I must calculate reimbursements for units dispensed in Massachusetts only.

B. The Drugs Relevant to the Sub-Classes Putatively Certified by the Judge

8. At page 2 of her *Memorandum and Order*, Judge Saris states, “Seventeen of the drugs at issue are reimbursed under Medicare Part B.”⁴ I have found that those drugs subject to reimbursement by one or all three of the Sub-Classes are more numerous (i.e., 27 in number) and are presented by Track One manufacturer in Table 2. Table 2 is the basis for the drugs included in the analysis and calculations developed in this Declaration. I calculate aggregate damages for the drugs in Table 2 for as much of the Class Period as possible using Defendants’ data production to date. Where it was not possible to calculate aggregate damages, due to insufficient data production by Defendants, I calculate aggregate damages using standard formulaic methodologies to extrapolate existing data to those periods for which data were incomplete.

⁴ More specifically, footnote 14 of the *Memorandum and Order* the Court states, “It is not clear how many physician-administered drugs are involved. Plaintiffs claim there are fifteen physician administered drugs and seventeen Medicare Part B drugs. Defendants state that there are thirty-five physician administered drugs but they do not disclose how many are covered by Medicare Part B.”

Table 2: Track One Defendants: Drugs Analyzed

Manufacturer	Drug Name
AstraZeneca	Pulmicort Zoladex
Bristol-Myers Squibb	Blenoxane Cytosan Etopophos Paraplatin Rubex Taxol Tequin Vepesid
GlaxoSmithKline	Alkeran Imitrex Kytril Lanoxin Myleran Navelbine Retrovir Ventolin Zofran Zovirax
Johnson & Johnson	Procrit Remicade
Schering Plough and Warrick	Albuterol Intron Perphenazine Proventil Temodar

C. The Focus of This Liability Declaration

9. In my Affirmative and Rebuttal Declarations in Support of Class Certification,⁵ I was directed to assume liability and develop and demonstrate a scientifically based and economically accurate method for calculating aggregate Class-wide damages for Sub-Classes defined by self-administered and physician-administered drugs. In the discussion of my formulaic methodology, I made use of preliminary calculations of actual spreads, yardstick spreads and total units of each relevant drug reimbursed by alternative Sub-Classes.

10. In this Declaration, I use the same formulaic methodology to demonstrate liability and causation by indicating the extent to which actual spreads did indeed exceed appropriate yardstick spreads for the drugs relevant to the Sub-Classes putatively certified by the Judge. Where sufficient discovery has been provided to make these calculations accurately,⁶ I use these spreads to calculate aggregate damages on the units reimbursed by the three Sub-Classes for the drugs of each of the five Track One Defendants. At direction of Counsel, I do not address issues of allocation at this stage of the litigation.

D. The Use of AWP for Determining Drug Reimbursement

11. In my September 3, 2004 Declaration in Support of Class Certification, I discussed the extent to which the End-Payor Sub-Classes identified therein relied upon

⁵ Throughout this Declaration, I refer to my previous declarations filed in this matter: Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification, September 3, 2004; Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification, December 16, 2004; Rebuttal Declaration of Raymond S. Hartman in Response to the Sur-Reply Declaration of Steven J. Young, March 9, 2005.

In addition, I refer to the following other declarations submitted in this matter: Declaration of Eric M. Gaier, PhD in Support of Defendants' Opposition of Class Certification, October 25, 2004; Sur-Reply Declaration of Eric M. Gaier, PhD in Support of Defendants' Opposition of Class Certification, January 21, 2005; Declaration of Steven J. Young in Opposition to the Plaintiffs' Motion for Class Certification, October 25, 2004; Sur-Reply of Steven J. Young in Opposition to the Plaintiffs' Motion for Class Certification, January 20, 2005; Report of Independent Expert Professor Ernst R. Berndt to Judge Patti B. Saris, February 9, 2005.

⁶ I note that I have not received from any Defendant the data (as requested for **all years and for all drugs**) sufficient to make a determination of liability and a calculation of damages for the complete Damage Period.

AWP for reimbursement payments. I concluded:

“The AWP (average wholesale price) is the industry benchmark for reimbursement for drugs administered under Medicare Part B and for all other drugs reimbursed subject to contracts and/or pricing formulae using AWP. AWP is interpreted by the industry as a measure of the underlying structure of drug prices. ... AWP is the glue that binds the informational network. Given its universality, the alleged AWP scheme impacted essentially all relevant pharmaceutical transactions.”⁷

12. The Court’s observations regarding this conclusion⁸ served as the basis for putative certification of **Sub-Classes 1 and 2**. The Court finds that the AWP was the basis for reimbursement for all or substantially all drugs reimbursed under Medicare Part B, even when drugs became multi-source, since the calculation of multi-source reimbursement was based upon generic AWP. The Judge finds that AWP continued to be the basis for Medicare reimbursement for Part B drugs until the basis was switched in 2005 **to the measure that I use most frequently for my yardsticks – the ASP**. In addition, the Judge appears to accept my contention (made in my September 3, 2004 Declaration) that the calculation of damages for the Sub-Classes 1 and 2 are formulaic.⁹

⁷ See the Executive Summary to that Declaration, pp. 1-2. I provide the foundation for this conclusion in ¶¶ 17, 19-25 of the September 3, 2004 Declaration and in Attachment D to that Declaration.

⁸ *Memorandum and Order*, pp. 14-16 and 57-59.

⁹ At pp. 58-60 of the *Memorandum and Order*, Judge Saris states (with **emphases added in bold**) for Sub-Class 1: “The Court is satisfied that as to the Medicare Part B beneficiary class, a class action is a superior method to resolve the dispute. Defendants have not identified any plausible individual issues that will arise with regard to these class members other than their proofs of damages, which may entail reviewing documents to determine whether each patient was required to pay a percentage-based co-pay and whether each has supplemental insurance. **These damages calculations will be largely formulaic.** Even if some corroboration and individualized attention is necessary, it is unrealistic to expect millions of beneficiaries across the nation to repeatedly prove these claims. The number of drugs at issue in the Medicare Part B context is limited to about seventeen, so even if deciding spreads by individual NDCs is necessary, it would not be unmanageable.”

For Sub-Class 2, she states: “**Again, the common factual issues (as outlined in the previous section) predominate**, in that the TPPs are required by contract to supplement Medicare drug co-payments. Some TPPs may have greater sophistication with respect to the existence of spreads because they purchase self-administered drugs, but there is no evidence that TPPs purchase physician-administered drugs or know of the mega-spreads that exist for these drugs. In any event, the reimbursement rate is set by statute, not negotiation. Therefore, there appear to be no factual differences with respect to reliance or causation that predominate over the common issues. Defendants have not pressed an extensive predominance challenge in this context regarding factual issues. ... Rather, defendants challenge class certification with respect to these TPPs primarily on the ground that the legal differences among the state consumer protection statutes predominate over the common legal questions. ... [As a result], the Court will certify a statewide class of TPPs that pay supplemental insurance covering Medicare Part B co-payments under Mass. Gen. Laws ch. 93A.”

13. Furthermore, in certifying **Sub-Class 2** (see footnote 9 above), the Judge articulates the finding that the AWP provided information to commercial payors that was insufficient to make informed decisions regarding the acceptance or rejection of claims for reimbursement of physician-administered drugs. Judge Saris states:

“Some TPPs may have greater sophistication with respect to the existence of spreads because they purchase self-administered drugs, but **there is no evidence that TPPs purchase physician-administered drugs or know of the mega-spreads that exist for these drugs**” (Emphasis added).

With respect to physician-administered drugs, this finding certainly accords with the analysis I put forward in my September 3, 2004 Declaration. I stated therein

“Given the lack of pricing transparency in this industry as discussed in Attachment C and given the widespread use of AWP as a pricing reference point, market expectations about the manufacturers’ ASPs and thus providers’ and other intermediaries AACs have been determined by a drug’s AWP. ... That is, they have expected that AWP is larger than ASP by *a reasonably predictable amount*” (§ 10.b).

“Exercise of market power, or power to move market share, by [Providers moving market share of physician-administered drugs] is facilitated by the overall lack of transparency of pricing signals in this industry. ... [T]he incentives to move market share are enhanced by a manufacturer *secretly increasing the spread between AWP and ASP (or AAC)*. The spread must be increased secretly, because if such spreads were understood to exist, competitors would behave to eliminate them” (Attachment C, § 35).

14. In certifying **Sub-Class 3**, the Judge continues to recognize the fact that the AWP is the basis of reimbursement. However, she raises certain questions regarding individual issues (at pp. 61-62):

“Plaintiffs seek to include as part of the physician administered class all TPPs that pay for physician-administered drugs outside the context of Medicare Part B and consumers that make percentage-based co-payments for these drugs under their private insurance plans. Defendants do not dispute that the class meets the numerosity/commonality/typicality/adequacy requirements of Fed. R. Civ. P. 23(a), and I find that it does. However, **defendants do argue that individual factual and legal issues predominate over common ones because (1) each TPP had a different level of knowledge regarding the spread; and (2) each TPP negotiated separate agreements with doctors or groups of doctors**” (Emphasis added)

She explores possible individual issues (at pp. 65-69) with a discussion of arguments raised by Defendants' expert Stephen Young. She also cites questions (pp. 69-70) raised by Dr. Berndt concerning the relevance of J-Codes. I address these issues in Sections VI and VII respectively.

15. However, it is useful to note briefly at this point that Judge Saris' conclusion regarding Sub-Class 2, that "there is no evidence that TPPs purchase physician-administered drugs or know of the mega-spreads that exist for these drugs," logically extends to the commercial payors included in Sub-Class 3. In light of that lack of knowledge, **one must be very careful in evaluating Defendants' claims cited by Judge Saris** (see ¶ 14 above) that "each TPP had a different level of knowledge regarding the spread; and [therefore that] each TPP negotiated separate agreements with doctors or groups of doctors." Since the Judge recognizes that there is no evidence supporting the assertion that TPPs knew of the "mega spreads," there is no reason to assume that "each TPP had a different level of knowledge regarding the spread" **relevant to the true ASP** which was the basis of the "mega-spreads."

It is true that different TPPs negotiated separate "agreements with doctors or groups of doctors." However, these separate reimbursement agreements were negotiated **relative to the reported AWP**. Since "there is no evidence that TPPs ... know of the mega-spreads that exist for these drugs," these negotiations simply could not have been shaped in any significant way by the existence of the "mega-spreads." That is precisely why the use of "mega-spreads" or large "Returns to Practice"¹⁰ was effective in moving market share.

The variation in the negotiated reimbursement rates relative to the actual AWP among TPPs in Sub-Class 3 is based upon factors recognized in the industry, including most importantly size, as reflected by the number of insured lives aggregated by the TPP.¹¹ The negotiation also relies upon an anticipation that the AWP provides a signal

¹⁰ See *United States of America v. TAP Pharmaceutical Products, Inc., Sentencing Memorandum of the United States*, United State District Court for the District of Massachusetts, Eastern Division, Criminal Action, No. 01-CR-10354-WGY (hereafter *Lupron Sentencing Memorandum*), Section VIII below and Attachment F to this Declaration.

¹¹ Dr. Gaier correctly states at ¶ 41 of his Rebuttal Declaration, "economic theory predicts that larger payors would invest more resources to leverage competition than smaller payors because every dollar

for the underlying spreads. Had the existence of the “mega-spreads” been perceived and understood by TPPs, those payors would have negotiated more aggressively than they did, leading to lower reimbursement rates. The lower reimbursement rates would have been related to the drug acquisition cost to the provider (or the ASP), which was well below the inflated AWP. Because the “mega-spreads” were not perceived, the reimbursement rates were negotiated relative to the artificially inflated AWP, which were in many cases 50%-1000% above the actual provider acquisition costs.

E. The Economic Incentives Motivating the Alleged Fraudulent Pricing Scheme

16. For all three Sub-Classes, I discussed incentives and the opportunities for the alleged pricing abuses for physician-administered and Medicare Part B drugs in Attachment F to my September 3, 2004 Declaration in Support of Class Certification. Regarding this, the Court states (emphases added in bold):

“Because doctors are involved as both retailers and as prescribing physicians, manufacturers, realizing the purchasing power of physicians, provide them with rebates, **leading to large profits for the doctors on the prescription and administration of certain drugs.** These profits now allegedly comprise a large percentage of these doctors’ income; according to Hartman, two thirds of the income of practice-based oncologists comes from the mark-up on injectable drugs. ... Some experts have commented that **‘the financial incentives created by this profitability played a large and problematic role in prescribing decisions’** from 1998-2003 because ‘prescribers responded to these high margins by tending towards administering more (and more expensive) drugs than might be medically necessary or optimal for the health of the patient.’”

“Because physician-administered drug reimbursement has been based on a five-digit ‘J-Code’ system, which does not differentiate for strength, dosage and

invested would accrue to more members. This theory is supported by record evidence from Coventry, with more than 2.4 million lives insured, and plaintiff Philadelphia Federation of Teachers Health and Welfare Fund (“Teachers”), with between 55,000 and 65,000 insured lives.”

Mr. Young correctly states at ¶ 126 of his Rebuttal Declaration, “The level of consideration, including drug reimbursement that Payors negotiate to pay PBMs is impacted by the Payors leverage in those contract negotiations. Among the most significant sources of a Payor’s leverage is the volume of lives it represents. Large Health Plans representing millions of lives may have more leverage, for example, than small union benefit funds with relatively small representation. That leverage allows the larger Health Plans to negotiate deeper discounts, lower administrative fees, up-front payments, and preferential rebates and guarantees.”

While TPP size may be more important in negotiations regarding reimbursement rates for self-administered drugs, size will also matter for physician-administered drugs.

packaging (unlike NDCs), the issue of pricing transparency becomes an ‘order of magnitude larger’ in this context (Berndt ¶ 199). In summary, when medical benefit expenditure data are poorly monitored and ‘tracking patient data is nearly impossible’, and when this is widely known, possibilities for mischief and abuse arise. That appears to be the case for physician-administered drugs adjudicated under the medical benefit (Berndt ¶ 191).”¹²

IV. My Yardstick Methodology Is Based on Standard Economic Theory and Can Be Implemented for All Three Sub-Classes

17. For the drugs reimbursed by the Sub-Classes recognized by Judge Saris, the yardstick methodology proposed in my September 3, 2004 Declaration in Support of Class Certification is relatively simple.

18. As the Court states (see footnote 9 above), for Medicare Part B drugs “the reimbursement rate is set by statute, not negotiation,” ... and “damages calculations will be largely formulaic.”¹³

¹² *Memorandum and Order*, pp. 29-31. Also note, on page 42 of his February 9, 2005 Report, Dr. Berndt further describes the lack of information that has characterized payor understanding of the actual spreads during the Class Period: “In a different industry publication, an executive at AdvancePCS reports that in his experience health plans become ‘flabbergasted at what they’ve been paying for years on drugs’ on the medical side because of dramatic price markups.”

¹³ It is useful to provide a brief summary of statutory provisions determining Medicare reimbursement for Part B drugs by time period.

Prior to 1992:

“Before 1992, Medicare carriers generally paid for drugs based on physicians’ estimated costs as measured by the AWP.” (Source: Medpac, “Report to Congress: Variation and Innovation in Medicare,” Chapter 9, “Medicare payments for outpatient drugs under Part B,” June 2003, pp. 152).

1992 through 1997:

“Payment for a drug ... is based on the lower of the estimated acquisition cost or the national average wholesale price of the drug. ... For multiple-source drugs, payment is based on the lower of the estimated acquisition cost ... or the wholesale price that, for this purpose, is defined as the median price for all sources of the generic form of the drug.” (Source: 42 CFR 405.517, Revised October 1, 1996).

From 1998 – 2003:

“Payment for a drug or biological ... is based on the lower of the actual charge on the Medicare claim for benefits or 95 percent of the national average wholesale price of the drug or biological. ... For multiple-source drugs and biologicals, for purposes of this regulation, the average wholesale price is defined as the lesser of the median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological. (Source: 42 CFR 405.517, Revised October 1, 2003).

More specifically, for single-source brand name drugs reimbursed by members of Sub-Classes 1 and 2,

- a) Prior to 1992, Medicare carriers took the AWP to be the physicians' estimated acquisition cost.
- b) From 1992 to 1997, reimbursement was set at the lesser of the estimated acquisition cost ("EAC") or AWP.
- c) On January 1, 1998, reimbursement was changed to the lesser of (1) the billed charge on the Medicare claim form or (2) 95% of AWP. This practice continued through 2003. While the statutory language changed to the "lesser of the billed charge" or 95% of the AWP, the understanding of "the billed charge" was the EAC of the drug, despite the fact that AWP was used systematically to determine reimbursement.¹⁴

For 2004:

"The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (DIMA) provides that as of January 1, 2004, the payment limits for drugs and biologicals are based on 85 percent of the April 1, 2003 Average Wholesale Price (AWP), for those drugs and biologicals furnished on and after January 1, 2004. ... The Medicare payment limits [%*AWP] for drugs and biologicals not paid on a cost or prospective payment basis, and furnished on or after January 1, 2004, through December 31, 2004, are as described" for a variety of specific Part B medications, including blood clotting factors; new drugs or biologicals (as approved by the FDA subsequent to April 1, 2003); pneumococcal and hepatitis B drugs and biologicals; certain drugs studied by the OIG and GAO; infusion drugs furnished through an item of implanted durable medical equipment; drugs and biologicals not described above. The percentage off AWP for these different medications varies from 80-95%, some based on the April 1, 2003 AWP.

From § 20.2: "For a single source drug or biological, the AWP equals the AWP of the single product. For a multi-source drug or biological, the AWP is equal to the lesser of: the median AWP of all generic forms of the drug or biological; or the lowest brand name product AWP. (Source: Department of Health & Human Services, Centers for Medicare & Medicaid Services, CMS Manual System, Pub. 100-04 Medicare Claims Processing, Transmittal 54, December 24, 2003).

From January 1, 2005:

"Per MMA of 2003, beginning 1/1/05, drugs and biologicals not paid on a cost or prospective payment basis will be paid based on 106% of the Average Sales Price (ASP). CMS will supply contractors with an ASP drug pricing file for payment of drugs. This pricing file shall be provided to contractors by CMS quarterly. Contractors will continue to price covered drugs not on the file." (Source: Department of Health & Human Services, Centers for Medicare & Medicaid Services, CMS Manual System, Pub. 100-04 Medicare Claims Processing, Transmittal 352, November 3, 2004).

¹⁴ I base this assertion on the following fact discovery and testimony.

- CMS statements. For example, in his March 21, 2002 testimony to the U.S. House Energy and Commerce Subcommittees on Oversight & Investigations and Health on Part B drug reimbursement, Thomas Scully, CMS Administrator, states "These drugs are typically provided in the hospital outpatient setting, dialysis centers, or in the doctor's office, and are purchased directly by the physician or provider. ... By law, we generally pay for these drugs based on the actual charge or 95 percent of the AWP, whichever is lower." He confirms this position in similar testimony to the Senate Finance Committee Subcommittee on Health, March 14, 2002.
- The alternative reimbursement basis before 1998 was EAC, and the alternative basis returned to EAC (= ASP) in 2005.

- d) From January 1, 2004 through December 31, 2004, drugs were generally reimbursed at 85% of AWP, with exceptions clarified in footnote 13.

19. Hence, as I stated at ¶ 33 of my September 3, 2004 Declaration, by statute the but-for spread for those single-source brand-name drugs reimbursed by Sub-Classes 1 and 2 was 0.0%; alternatively, the but-for reimbursement was the EAC = ASP. This is true for 1991 through 2003. Under the amendments for 2004, the amended statute makes no appeal to a “billed charge” or “EAC;” single-source drugs are reimbursed at a percentage (default = 85%) of AWP. For claims reimbursed by Sub-Classes 1 and 2 in 2004, damages for Medicare Part B single-source drugs arise to the extent that the actual AWP was artificially inflated above the “but-for AWP”. Damages are then calculated as $85\%^{15} * (AWP - AWP_{\text{but-for}})$. In 2005, Congress set reimbursement at the $106\% * ASP (= AWP_{\text{but-for}})$. I do not calculate damages for Medicare Part B for 2005.

20. For multi-source drugs reimbursed by members of Sub-Classes 1 and 2, there is greater nuance (see footnote 13). Specifically,

- a) Prior to 1992, reimbursement was set at the AWP which was taken as the measure of the EAC.
- b) From 1992 through 1997, reimbursement was set at the lower of EAC or the wholesale price defined as the median of the AWP of all generic forms of a drug.
- c) On January 1, 1998, reimbursement was changed to the lower of the billed charge or 95% of an average wholesale price defined to be the lower of the median of the AWP of all generic forms of a drug or the AWP of the least expensive brand-name drug.¹⁶
- d) From January 1, 2004 to through December 31, 2004, reimbursement was changed to 85% of an AWP defined to be the lesser of the median AWP of all

This understanding is reflected in Defendants’ expert Steven Young’s testimony: “From 1992 to date, moreover, reimbursement under Medicare Part B has generally been made at the lower of the billed charge amount or AWP (through 1997) or 95% of AWP (after 1997). The Carriers may reimburse at less than the AWP based rates where, for instance, the physicians’ billed charges are less” (Young October 25, 2004 Rebuttal Declaration at ¶ 170).

¹⁵ Or from 80% to 95% for certain drugs and biologicals; see footnote 13.

¹⁶ This interpretation (from footnote 13) is further confirmed in DHHS, HCFA Program Memorandum Intermediaries/Carriers Transmittal No. AB-00-110, November 14, 2000 and Transmittal AB-00-117, November 30, 2000.

At pages 14-16 of the *Memorandum and Order*, Judge Saris appears to have slightly misstated the statute with respect to multi-source drugs for the 1998-2003 period.

generic forms of the drug or biological or the lowest brand name product AWP (see footnote 13).¹⁷

Hence, as with single-source brand-name drugs, the ASP was the “but-for AWP” for 1991-2003, and the “but-for spread” was 0.0%. With the statutory revision in 2004, the alternative reimbursement rate was no longer the ASP. While reimbursement rates were still artificially inflated to the extent that AWP’s were inflated, with multi-source drugs, the calculation of the potential but-for AWP’s requires ASP data for many additional manufacturers, data which were unavailable to me. For that reason, for multi-source Part B drugs, I do not calculate damages for Sub-Classes 1 & 2 for 2004 through the present.

21. The Court characterizes¹⁸ the yardstick methodology I propose for non-Medicare TPP and consumer reimbursement (Sub-Class 3) as follows:

“Hartman intends to calculate the spreads for the drugs allegedly subject to the AWP scheme and compare those spreads to ‘but for’ spreads, that is,

- Spreads for comparable drugs that are unaffected by the AWP scheme and fraud.
- As a cross-check, he will compare the calculated ‘but for’ spread with industry-wide surveys.
- In addition, under the ‘revealed preferences’ method, Hartman will calculate the expected spread by examining the contracts for the drugs affected by the alleged fraud to determine what the parties expected the spread between AWP and the ASP to be, and compare that expected spread with the actual spread. (Hartman Rebuttal ¶ 50 (‘Simply stated, economic agents reveal their preferences, and implicitly the information they relied on, by their actual market decisions and behavior.’).”

She concludes, “Hartman terms his overall approach the ‘yardstick method’¹⁹ because he intends to determine what the market reasonably expected the spread to be on average

¹⁷ Judge Saris makes no mention (at p. 15 of the *Memorandum and Order*) of a change in reimbursement procedures for multi-source drugs beginning in January 2004.

¹⁸ *Memorandum and Order*, pp. 63-65.

¹⁹ The notion and use of a “yardstick method” has a long and venerable tradition in economic theory and applied economic analysis. It has been utilized in many contexts including, but by no means limited to, the following:

- Legal analysis of thresholds for a determination of tacit collusion; see for example, D.A. Yao and S.S. DeSanti [1993], “Game Theory and the Legal Analysis of Tacit Collusion,” *Antitrust Bulletin, Symposium on Tacit Collusion*, 38(1).

(e.g., AWP is 25% above the average sales price, ASP), and compare this number to the actual spread (e.g., AWP is 100% above ASP) to calculate aggregate Class-wide damages.”

22. I have implemented this yardstick methodology.

- a) First, I have identified single-source comparator pharmaceuticals, both orals and physician-administered, by therapeutic indication. I have identified the evolving therapeutic competition they faced over the period 1989 through the present. The relevant drugs are presented in Table 3. Table 3.A presents single-source self-administered innovator drugs; physician-administered drugs are presented in Table 3.B. I intend to continue analyzing data to develop additional comparators and have asked Counsel to obtain the requisite data.

As recognized by the Judge (§ 16 above), the alleged AWP scheme was designed and implemented to move market share relative to the therapeutic competitors.²⁰ In the absence of therapeutic competition, a given manufacturer would find it unnecessary and unprofitable to increase spreads to move market share;²¹ if

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- Tax-setting behavior by U.S. states; see for example, T. Besley and A. Case [1995], “Incumbent Behavior: Vote-Seeking, Tax-Setting, and Yardstick Competition,” *American Economic Review*, 85(1), March.
 - Regulating the cost, performance and/or pricing of natural monopolies and public enterprises; see for examples, Roger Sherman [1989], *The Regulation of Monopoly*, Cambridge University Press, pp. 73, 285, 1989; and W.W. Cooper [1943], “The Yardstick for Utility Regulation,” *Journal of Political Economy*, 51(3); A. Shleifer [1985], “A Theory of Yardstick Competition,” *Rand Journal of Economics*, 16(3); F.M. Scherer [1980], *Industrial Market Structure and Economic Performance*, chapter 18; J. Rosellion and J. Halpern, “Regulatory Reform in Mexico’s Natural Gas Industry,” World Bank Report, Latin American and the Caribbean Region.
 - To strategically manage managerial performance; see for example, Jean Tirole [1995], *The Theory of Industrial Organization*, chapter 2.2; and B.R. Holmstrom and J. Tirole [1989], “The Theory of the Firm,” *Handbook of Industrial Organization*, chapter 2, Volume 1.
 - To strategically induce research and development; see for example, Jean Tirole [1995], *The Theory of Industrial Organization*, chapter 10.4.
 - Regulating insurance premia; see for example, Irving H. Plotkin, “Total Rate of Return and the Regulation of Insurance Profits,” Arthur D. Little Report, Presented at the May 1979 Meetings of the Casualty Actuarial Society, chapter IV.
 - Analysis of the performance of Social Security; see for example, W.W. Beach and G. G. Davis [1998], “Social Security’s Rate of Return: A Reply to Our Critics,” Report of the Heritage Center for Data Analysis.

In all of these applications, actual economic or market results and/or behaviors are compared with an appropriate yardstick or set of yardsticks (i.e., but-for measures) to determine whether the actual market results and/or behaviors meet certain legal, regulatory and/or managerial standards. My yardstick analysis is used precisely in the same way – to assess whether actual pricing behavior of Defendants met or failed to meet non-fraudulent pricing behavior standards.

²⁰ See footnote 18 of my September 3, 2004 Declaration in Support of Class Certification, Attachment E to that Declaration, and the *Lupron Sentencing Memorandum*.

²¹ These comparator drugs include unique breakthrough innovator drugs developed for particular clinical uses and competitive innovator drugs that had been unique but came to face therapeutic competition over

Table 3: Drugs of Interest for Yardstick Analysis**TABLE 3.A BREAKTHROUGH SELF-ADMINISTERED INNOVATOR DRUGS****1. Proton-Pump Inhibitors**

From 1989 to 1995, Prilosec was the only PPI on the market and would have exerted considerable market power for the treatment of severe acid reflux and ulcers.

Brand	Generic	Manufacturer	Introduced	First Generic
Prilosec	omeprazole	AstraZeneca/Merck	1989	2002
Prevacid	lansoprazole	TAP/Abbot/Takeda	1995	
Protonix	pantoprazole	AHP/Wyeth	2000	
Aciphex	rabeprazole	Johnson & Johnson	1999	
Nexium	esomeprazole	AstraZeneca	2001	

2. Atypical Antipsychotics

From 1989 to 1993, Clozaril was the only atypical antipsychotic (meaning far fewer side effects than traditional antipsychotics) on the market and was a major breakthrough product.

Brand	Generic	Manufacturer	Introduced	First Generic
Clozaril	clozapine	Novartis	1989	1998
Risperdal	risperidone	Johnson & Johnson	1993	
Zyprexa	olanzapine	Eli Lilly	1996	
Seroquel	quetiapine	AstraZeneca	1997	
Geodon	ziprasidone	Pfizer	2001	

3. Non-Sedating Antihistamines

From 1993 until 1996, Claritin was the only option to traditional sedating histamines like Benadryl.

Brand	Generic	Manufacturer	Introduced	First Generic
Claritin	loratidine	Schering-Plough	1993	became OTC, 2002
Allegra	fexofenadine	Aventis	1996	
Clarinx	desloratidine	Schering-Plough	2002	

4. Bisphosphonates for Osteoporosis

Fosamax was a breakthrough drug for the treatment of osteoporosis – it was the first non-hormonal treatment to prevent bone loss. It had three years on the market as the only drug in its class.

Brand	Generic	Manufacturer	Introduced	First Generic
Fosamax	alendronate	Merck	1995	
Actonel	risedronate	Aventis	1998	

Table 3: Drugs of Interest for Yardstick Analysis**5. Phosphodiesterase Inhibitors for Erectile Dysfunction**

Viagra was a major breakthrough drug, enjoying five years on the market without a competitor.

Brand	Generic	Manufacturer	Introduced	First Generic
Viagra	sildenafil	Pfizer	1998	
Levitra	varafenafil	Bayer	2003	
Cialis	tadalafil	Eli Lilly	2003	

6. SSRI's

After 1992, there were three comparable products – Prozac, Paxil, and Zoloft – all on the market. But from 1987 - 1991, Prozac was THE breakthrough drug.

Brand	Generic	Manufacturer	Introduced	First Generic
Prozac	fluoxetine	Eli Lilly	1987	2001
Zoloft	sertraline	Pfizer	1991	
Paxil	paroxetine	GlaxoSmithKline	1992	2003
Celexa	citalopram	AstraZeneca	1998	2004
Lexapro	escitalopram	Forest	2002	

TABLE 3.B PHYSICIAN-ADMINISTERED DRUGS**1. Prostate Cancer**

Brand	Generic	Manufacturer	Introduced	First Generic
Lupron	leuprolide acetate	TAP	1988	1998
Zoladex	goserelin acetate	AstraZeneca	1987	n/a

2. Serotonin 5-HT3 Blockers (Antiemetics)

Zofran & Kytril have been therapeutic substitutes for over a decade; the generic version of Zofran has

Brand	Generic	Manufacturer	Introduced	First Generic
Zofran	ondansetron	GlaxoSmithKline (Glaxo)	1991	n/a
Kytril	granisetron	GlaxoSmithKline (SB)	1994	n/a
Anzemet	dolasetron	Aventis	1997	n/a
Aloxi	palonosetron	MGI	2003	n/a

uniquely efficacious, the clinical profile of the drug would be sufficient to move market sales. Hence, successful “break-through” innovator drugs serve as reasonable yardsticks for “but-for” spreads, specifically, for spreads that would be anticipated in the market in which spread manipulation was unnecessary to move market share for single-source branded drugs reimbursed by Sub-Class 3.

I have asked Counsel for discovery materials to allow me to calculate the spreads for those self-administered oral and physician-administered drugs in Tables 3.A and 3.B respectively for the relevant time periods. I discuss the production of data to date and my analysis of that data in Section VIII below.

- b) Second, “as a cross check,” I have reviewed (in my September 3, 2004 Declaration), and have continued to attempt to identify and review, publicly available sources providing market-wide information concerning the relationship between AWP and ASP for branded and generic self-administered and physician-administered drugs (§§ 28-33 of my September 3, 2004 Declaration). The notable examples, cited previously, for physician-administered drugs include the 1992 OIG report for New York State (NYS) chemotherapy drugs, which was broadened in 2001 by the American Society of Clinical Oncology (ASCO) to more single-source physician-administered drugs. Based upon these two sources, the yardstick spreads were 11%-25% (see ¶ 30.a) of my September 3, 2004 Declaration).²²

It is useful to note further that in my review of public information, the range of yardsticks for single-source self-administered innovator drugs found in the various OIG reports spanning the period 1984-2002 was 18%-28% (see ¶ 21, Attachment D to my September 3, 2004 Declaration).

- c) Finally, as noted by the Court, in order to further implement a revealed preference analysis of actual contract reimbursement rates, I have requested of Counsel additional discovery of contracts specifically between TPPs and providers of physician-administered drugs (i.e., doctors, oncology groups, clinics, out-patient hospital settings). The contract discovery I have reviewed to date, some of which is reflected in Attachment C, demonstrates that TPPs have negotiated to reimburse physician-administered drugs at (AWP – 16%) to (AWP + 15%).²³ It is interesting to note that this is almost precisely the range found by the MedPAC

time. These comparator drugs were either not subject to this litigation, or were subject to this litigation but are included as comparator drugs during that period when they were the single-source unique therapeutic alternative available on the market.

²² When I hypothesized that rebates could amount to 5% (see ¶ 30.d of my September 3, 2004 Declaration), my estimate of the yardstick spreads became 18%-33%. However, it has been noted that for physician-administered drugs, rebates are usually not paid to providers. Indeed, the Judge has recognized this fact; see *Memorandum and Order*, p. 29. My analysis of Defendants’ rebate data has confirmed this fact. Therefore, the 11-25% range of yardsticks is the appropriate range.

²³ Indeed, the contracts presented in Attachment C were produced as Defendants’ materials during the Class Certification Phase; I still await the discovery materials I since have requested of Defendants.

Report;²⁴ specifically MedPAC finds AWP \pm 15%. The Court has noted (at p. 64), “In the physician-administered context, the [contract] range is AWP minus 0% to 10%.”²⁵

23. Based upon these discovery materials, data analysis and publicly available survey information, I calculate the relevant yardsticks for Sub-Class 3 in Section VIII below.

V. Variability Within a Sub-Class is Addressed by Accepted Economic Techniques

24. All markets, without exception, are characterized by variation. Indeed, it is a primary hallmark of the science and practice of microeconomics to account for variability within markets, and by accounting for that variability achieve reasonably accurate aggregate calculations or estimations of quantifiable information. It may further be said that a significant purpose of applied economics and microeconomics is to explore the variability inherent in marketplaces, explain that variability, and account for it in summary information that enable one to draw meaningful aggregate conclusions about complex economic behaviors.

25. Among the methods employed in order to explore and address variability within a class, subclass or any group of economic individuals or entities is the use of average measures and the calculation of an aggregate damages amount. It must be emphasized, however, that the use of average measures is not an effort to ignore the variability or complexity of the members of a class or subclass. It is in fact a standard statistical method used to directly address that variability in order to calculate meaningful measures and accurate, aggregate outcomes (in these circumstances, an aggregate damages estimation).²⁶

²⁴ Medicare Payment Advisory Commission (MedPAC), Report to the Congress, *Variation and Innovation in Medicare*, June 2003 (MedPAC Report); Table 9-2.

²⁵ As noted by the Court (*Memorandum and Order*, p. 64), with respect to single-source self-administered innovator drugs, TPPs have revealed very narrow contract preferences regarding discounts off AWP: “Hartman estimates that the range of actual reimbursement rates in TPP contracts with providers in the self-administered context was AWP minus 13% to 17% (Hartman Decl. ¶ 30(g)); Young uses the range of AWP minus 14% to 18% (Young ¶ 134).”

²⁶ In this regard, I can see how the use of the term “average measures” might inappropriately denote a sort of “rounding off” or otherwise avoiding complexity or variability. In the area of applied economics and

26. The concern about variability and averaging is less important for Sub-Classes 1 and 2; they are largely formulaic, as recognized by the Court. For these Sub-Classes, the actual reimbursement rate (and the 20% co-insurance amount) has been some percentage of AWP, while the but-for reimbursement rate (and the but-for 20% co-insurance amount) was the ASP.

27. The use of averaging is primarily relevant to Sub-Class 3. While an expert must be careful that the averages used in the formulaic methodology are sufficiently representative of the Class being analyzed and for which aggregate damages are being calculated, the use of average measures constitute a standard approach to measuring aggregate damages.²⁷

As I note above (¶¶ 24-25) and state in ¶ 39 of my December 16, 2004 Rebuttal Declaration, "it must be noted that all markets, without exception, are characterized by variation." There will be variation among payors in their ability to negotiate reimbursement rates relative to the perceived AWP. The use of averages overcomes the concerns about variability, as was discussed previously in my December 16, 2004 Rebuttal Declaration. **More importantly, it must be noted that the variation among**

microeconomics, however, the use of average measures actually enables one, on an aggregate basis, to address and accommodate variability across the members of the class.

This ambiguity perhaps leads the Court to be unduly ambivalent about the use of average measures. For example, the Court states (*Memorandum and Order*, p. 63) "It is not permissible to use methods such as averaging damages to sweep individual issues under the judicial rug." My use of averaging does not "sweep individual issues under the judicial rug."

²⁷ As I have discussed at some length in my previous Declarations, my approach is used routinely in the scientific literature. See for examples, Daniel Rubinfeld, "Reference Guide on Multiple Regression" (pp. 179-227); Robert E. Hall and Victoria A. Lazear, "Reference Guide on Estimation of Economic Losses in Damages Awards," (pp. 277-332); both found in *Reference Manual on Scientific Evidence*, Second Edition, 2000, Matthew Bender Publishing Co; and Raymond Hartman and Michael Doane, "The Use of Hedonic Analysis for Certification and Damage Calculations in Class Action Complaints," *The Journal of Law, Economics and Organization*, Fall 1987.

Likewise, the approach is used regularly in litigation. In all of the Hatch Waxman litigation and the Lupron litigation in which I submitted Declarations in support of Class Certification, calculated damages, and or submitted damage calculations supporting settlement agreements, I have used analogous methods that make use of averages; see footnotes 2-12 in my September 3, 2004 Declaration. Such methods have been used in calculating aggregate damages in litigation with much greater variation among Class members than that revealed here; see footnote 82 of my December 16, 2004 Rebuttal Declaration. Such methods have been employed by Defendants' Experts Young, Gaier, and White in their consulting or academic research; see footnotes 16, 81-83 and Attachment F of my December 16, 2004 Rebuttal Declaration. Such methods have been used by other research groups; see Attachment F of my December 16, 2004 Rebuttal Declaration.

Class members in this matter is overwhelmingly dwarfed by the size of artificial AWP inflation. Specifically, the variation in negotiated reimbursement rates relative to the actual artificially inflated AWP is reasonably bounded by $\pm 15\%$; see the MedPAC Report. The size of the AWP inflation (measured by the “Spread,” as developed in my previous Declarations and as implemented in Sections VIII and IX below) is 25%-1000%, with some measures exceeding 1000%. Hence, **the measure of injury** (i.e., the artificial inflation of the AWP) **vastly overwhelms the measure of variation among Class members** in their ability to negotiate reimbursement rates. In the face of such measures of overall damage to the Class as a whole, a small amount of variation among Class members does not affect the reasonableness of the aggregate damages calculation.

28. Let me make these opinions more intuitive by adapting the graphical presentation in Sections IV and V of my December 16, 2004 Rebuttal Declaration.

- a) The Judge,²⁸ other experts, other survey research and I appear to agree that reimbursement rates negotiated by TPPs with providers for physician-administered drugs are related to AWP.
 - The MedPAC Report demonstrates TPPs reimburse for physician administered drugs on average at $97.5\% \times \text{AWP}$, with the range of the percentage being (85%-115%).
 - Discovery materials (Attachment C to this Declaration), indicate that providers submit claims to TPPs for reimbursement based upon the AWP, claims that are distributed around the actual (i.e., **artificially inflated AWP** = AWP_{ai}) as portrayed in Figure 1.B.²⁹
- b) The distribution of the reimbursement rates allowed on all claims, relative to AWP_{ai} , is summarized by their average in Figure 1.B. Note that the variation of negotiated reimbursement rates around the artificially inflated AWP (AWP_{ai}) is relatively small ($\pm 15\%$), as suggested by fact evidence.
- c) As the Court has stated (at p. 60), while “some TPPs may have greater sophistication with respect to the existence of spreads because they purchase self-administered drugs, ... there is no evidence that TPPs purchase physician-administered drugs or know of the mega-spreads that exist for these drugs.” Note

²⁸ At p. 65 of the *Memorandum and Order*, the Judge refers to one aspect of this earlier analysis as follows, “Hartman ... proposes using each TPP’s actual contract reimbursement rate (e.g., AWP minus 15%) to determine what rate the TPP would have paid in the but-for world, on the assumption that the actual contract rate takes into account the knowledge and market power of each TPP. (Hartman Decl. attach. F ¶¶ 4-5; Hartman Rebuttal ¶¶ 54, 58, fig. 1-C.)”

²⁹ As the Court will recognize, Figures 1.A-1.C are adaptations to physician-administered drugs of Figures 1.A-1.C of my December 16, 2004 Rebuttal Declaration.

Figure 1.A

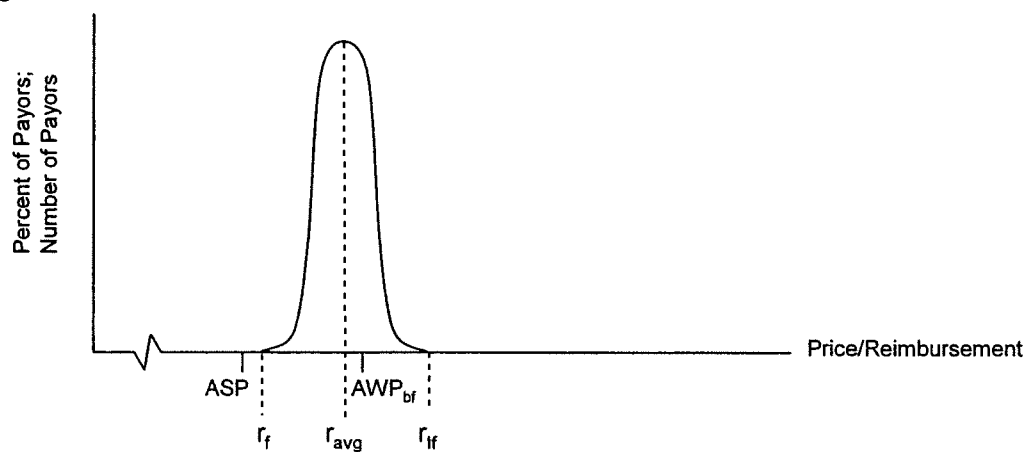


Figure 1.B

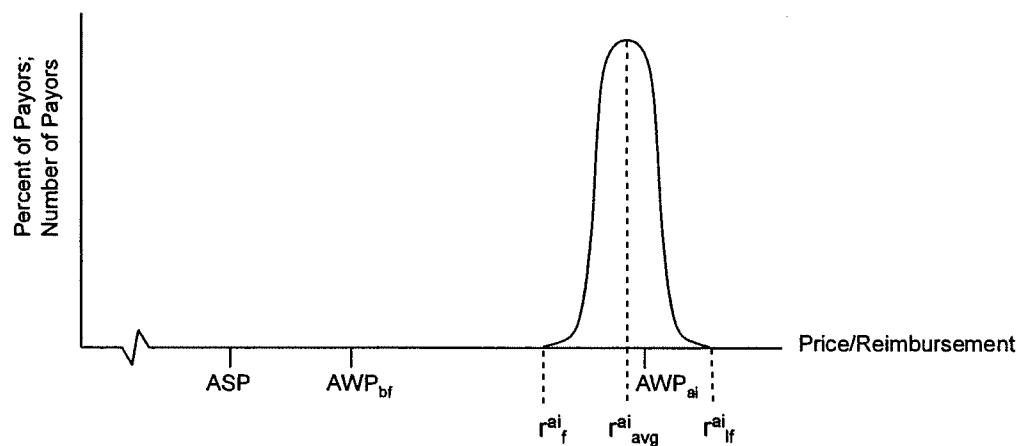
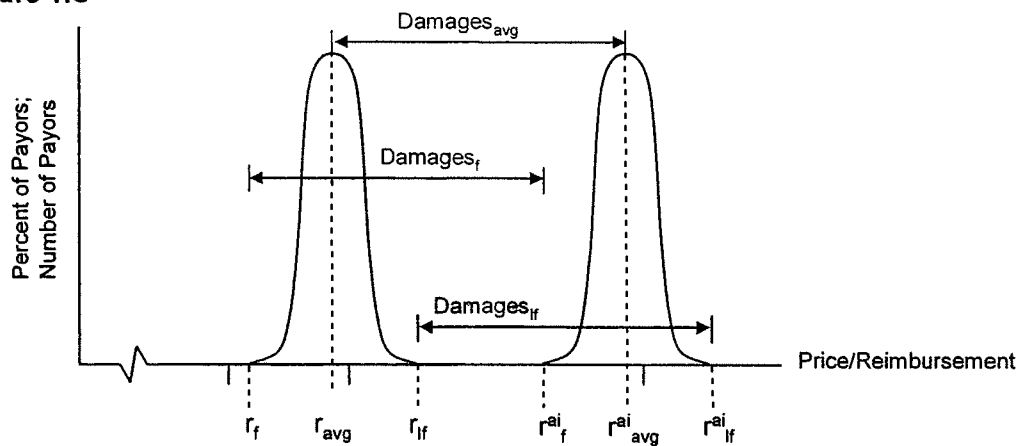


Figure 1.C



the existence of such “mega-spreads” indicates that the actual ASP is **substantially below** the actual AWP [i.e., $(AWP_{ai} - ASP)/ASP$ is 50% to 1000%] and **substantially below** the actual distribution of reimbursement rates (see Figure 1.B).

- d) If the AWP related to the ASP in ways **reasonably expected** by the TPPs and measured by the yardsticks (i.e., as the but-for AWP = $AWP_{but-for} = AWP_{bf}$), then the bell-shaped distribution of reimbursement rates would be those found in Figure 1.A. This distribution can also be summarized by an average, which is also standard statistical practice.
- e) This distribution summarizes the variation in reimbursement rates among Class members. It is also relatively narrow.
- f) Both distributions summarizing variation among Class members are vastly smaller than the difference in AWP induced by the alleged inflation; $AWP_{ai} > AWP_{bf}$.³⁰
- g) Aggregate damages are calculated using the averages in Figure 1.C, precisely as I have discussed more generally in ¶¶ 47 – 61 and Figures 1.A-1.C of my December 16, 2004 Rebuttal Declaration.³¹
- h) Implementation of this method for the calculation of aggregate damages to the Sub-Classes relevant to this matter appears in Section VIII.

29. I have already demonstrated in Attachment F to my September 3, 2004 Declaration, that the use of average measures of injury provide **an accurate calculation**

³⁰ Note that if the actual spread is 1000% and the but-for spread is 30% (see Section VIII below), then the AWP inflation relative to the drug acquisition cost (ASP) is 970%. Specifically, if $(AWP_{ai} - ASP)/ASP = 10$ and $(AWP_{bf} - ASP)/ASP = 0.30$, then $(AWP_{ai} - AWP_{bf})/ASP = 9.70$ (or 970%).

³¹ Note that in ¶ 45 of his Rebuttal Declaration, Dr. Gaier attempts to rebut my calculation as follows: “Consider Dr. Hartman’s proposed actual reimbursement rate (AA): $AA = AWP - x\% + df$, and his proposed but-for reimbursement rate ($AA^{but-for}$): $AA^{but-for} = AWP^{but-for} - x\% + df$, where $x\%$ stands for the discount from AWP obtained by the payor and df stands for the dispensing fee. By Dr. Hartman’s methodology, damages are based on actual reimbursement rates less but-for rates. The flaw in Dr. Hartman’s logic is his *assumption* that the discount from AWP (the $x\%$ term) remains constant between the actual and the but-for scenario. In fact, a payor that sufficiently leveraged competition to dissipate the effects of the alleged AWP scheme would receive a lower discount (i.e., $x\%$) in the but-for world than in the actual world. Thus, Dr. Hartman’s methodology does not allow for the possibility that competition would dissipate the alleged inflation.”

Given the fact discovery in this case, the Court correctly recognizes that payor’s **are not leveraged** to know the extent of the AWP scheme or to act upon such knowledge, if they possessed it. Furthermore, given Dr. Berndt’s research supporting the “importance of [all drug costs] being unimportant” (“The U.S. Pharmaceutical Industry: Why Major Growth in Times of Cost Containment?” *Health Affairs*, 20(2), 2001) relative to containment of increases in all managed health care costs, it is not surprising that the small component of all TPP reimbursements reflected by **physician-administered drug costs alone**, a component that is very expensive to monitor, is not subjected to scrutiny sufficient enough to adjust $x\%$ with variation in the AWP used for calculating allowed amounts.

of the summation of individual payor damages if the averages are calculated correctly.³² Again, it is my understanding that at this stage of the litigation, this is all that is required.

Allocation of the aggregate damages to individual Class members (or groups of Class members) will occur at the Claims Administration Phase and the data such as those introduced in my hypotheticals (in my Attachment F to my September 3, 2004 Declaration) will allow for informed allocation of aggregate damages.

30. Indeed, while addressing issues of allocation at p. 65, Judge Saris accurately describes my formulaic approach for calculating aggregate Class-wide damages and for allocating individual damages at the Claims Administration Phase:

“Hartman does not go into much detail on how to apportion individual damages in Phase II, but he proposes using each TPP’s actual contract reimbursement rate (e.g., AWP minus 15%) to determine what rate the TPP would have paid in the but-for world, on the assumption that the actual contract rate takes into account the knowledge and market power of each TPP. (Hartman Decl. attach. F ¶¶ 4-5; Hartman Rebuttal ¶¶ 54, 58, fig. 1-C.)”

This is a good summary of my proposed formulaic methods for calculating aggregate damages and individual Class member damages for Sub-Class 3. Figure 1.C above assists in distinguishing the relationship between the calculation of aggregate Sub-Class-wide damages and the allocation of individual damages for Sub-Class 3.

- a) While average discounts from the inflated AWP and the but-for AWP will determine and allow for calculation of aggregate damages, the damages of individual Class members will be determined by the actual discounts from AWP reflected in the claims they put forward at the time of Claims Administration.
- b) For example, using the findings in the MedPAC Report (see ¶ 22 above), commercial payors reimburse for physician administered drugs in a non-Medicare setting on average at 97.5%*AWP, or AWP – 2.5%. This fact will be used to calculate aggregate Class-wide damages.

³² The hypotheticals allowed for groups of payors to be differentiated by their ability to aggressively negotiate discounts off AWP in the reimbursement contracts with providers. As discussed by Defendants experts, the size of the TPP, in terms of insured lives, has been cited as a major factor in the ability to negotiate favorable discounts off AWP; see footnote 11 above. Other hypotheticals could be developed demonstrating that the use of average measures over representative samples of Class members will provide damage calculations exactly equal to the summation of damages to each and every individual payor. In the real world, use of average measures of injury will provide a sufficiently precise calculation of the summation of individual payor damages.

- c) However, some individual payors possess considerable bargaining power and are able to negotiate favorable reimbursement rates at AWP – 15% (i.e., r_f^{ai} and r_f in Figure 1). Other commercial payors have little bargaining power and can only negotiate least favorable reimbursement rates at AWP + 15% (i.e., r_{lf}^{ai} and r_{lf} in Figure 1). Other payors will fall in between. These findings will support allocation at the Claims Administration Phase.³³
- d) This approach will be applicable to all physician-administered drugs reimbursed by members of Sub-Class 3 at allowed amounts related to the AWP of the relevant NDC or the AWP of the fundamental billing unit of the relevant J-Code (see Section VII below).

31. I conclude that individual issues do not predominate at this stage of the litigation; that they will not interfere with the calculation of aggregate Class-wide damages using average measures; and that they will not prevent proper allocation during the Claims Administration. As I have stated above, at direction of Counsel, I do not address issues of allocation in this Declaration at this stage of the litigation.

VI. The Specific Objections Raised by Defendants' Experts Are Without Merit

32. The Court (at pp. 68-70)³⁴ observes the following criticisms put forward by Mr. Young:

- “Defendants’ expert Stephen Young, who is not an economist but has industry experience as a consultant, attacks Hartman’s expert methodology by arguing that
- (A) most commercial payors did not negotiate with physicians based on their drug acquisition costs, and even if they did they did not premise those negotiations on the view that AWP was a ‘signal’ of acquisition costs;
- (B) the reimbursement attributable to a particular physician-administered drug, and the rationale for that reimbursement, cannot be assessed without a consideration of the entire fee schedule of negotiated services;
- (C) because of the use of the ‘J-Codes’, the analysis of physician-administered drugs will require significant individual inquiry in a manual process to determine the reimbursement level; and

³³ For example, at the Claims Administration Phase, I will look at damage measures for these groups (and others if relevant) of individual Sub-Class members ($(r_{lf}^{ai} - r_{lf})$ and $(r_f^{ai} - r_f)$) to assist in allocating aggregate damages.

³⁴ The Judge essentially lists the points raised in ¶ 4 of Mr. Young’s Sur-Reply.

(D) unlike in retail pharmacy reimbursement, AWP is not consistently referenced in contracts for the reimbursement of physician-administered drugs.”

As a matter of economics, pharmaceutical business practices, fact evidence and deponent and expert testimony, these assertions are without merit and fail. Mr. Young has made several of them in his earlier Rebuttal testimony, and I have demonstrated in my Rebuttal testimony³⁵ that the assertions are without merit. Because a full response to these assertions reiterates portions of my earlier testimony, I provide relevant portions of that earlier testimony in Attachment K.

33. Mr. Young’s first incorrect assertion is that

“Most commercial payors did not negotiate with physicians based on their drug acquisition costs, and even if they did they did not premise those negotiations on the view that AWP was a ‘signal’ of acquisition costs.”

Mr. Young has made such a claim for both self-administered oral and physician-administered drugs. In the current context, its relevance is obviously narrowed to physician-administered drugs. However, Mr. Young’s own testimony and the testimony of fact witnesses upon whom he relies clearly demonstrate that payors did indeed understand AWP to be a signal for the provider acquisition costs of both types of drugs. Specifically,

- a) Mr. Young testifies that payors understood that AWP signaled providers’ acquisition costs for self-administered oral drugs.
- b) He testifies that payors understood that reimbursement rates calculated as a percentage off AWP covered those drug acquisition costs and a “competitive” margin to provider pharmacies.
- c) Mr. Young testifies that the same payor understanding of a relationship between AWP and provider acquisition cost extended to physician-administered drugs under Medicare Part B reimbursement.
- d) Survey research demonstrates that the same understanding of a relationship between AWP and provider acquisition cost extended to physician-administered drugs under non-Medicare payor reimbursement.
- e) While payors understood that the relationship between AWP and provider acquisition costs was changing by the end of the 1990s, they continued to use

³⁵ See my December 16, 2004 Rebuttal Declaration.

AWP as the basis for reimbursement, as recognized by the Court, Mr. Young and Dr. Berndt.³⁶

34. I conclude that the evidence and Mr. Young's own testimony demonstrate that commercial payors did have expectations regarding the relationship between reimbursement rates based on AWP and provider acquisitions costs for physician-administered drugs reimbursed under Medicare Part B and in non-Medicare settings. I quantify those expectations in my yardstick analysis in Section VIII below.

35. Mr. Young's second incorrect assertion is that

"The reimbursement attributable to a particular physician-administered drug, and the rationale for that reimbursement, cannot be assessed without a consideration of the entire fee schedule of negotiated services."

I have addressed this incorrect assertion more generally in Section VII of my December 16, 2004 Rebuttal Declaration. I address it more fully in Attachment K to this Declaration.

I find that TPPs must have and did look to signals for the costs of each of the factors (including the drugs administered) and services required during negotiations for contracts involving physician-administered drugs. If, during negotiations, incomplete or incorrect signals are given for individual components of the medical service to be provided, the total reimbursement rate allowed for the medical benefit will be incorrect. If the signal is inflated for the actual costs of a given component (i.e., the AWP of the drug administered is inflated), commercial payors will be overcharged.

36. Mr. Young's third incorrect assertion is that

"Because of the use of the 'J-Codes', the analysis of physician-administered drugs will require significant individual inquiry in a manual process to determine the reimbursement level."

Because the relevance of J-Codes is important, I defer response to this assertion to Section VII below.

37. Mr. Young's fourth incorrect assertion is that

³⁶ See Attachment K to this Declaration for a more complete development of these statements.

“Unlike in retail pharmacy reimbursement, AWP is not consistently referenced in contracts for the reimbursement of physician-administered drugs.”

Whether the AWP is referenced in contracts or not is not really relevant.³⁷ The crucial factor is what do TPPs rely upon and expect to be reflected in the invoices received from physicians for medical benefits. Survey research demonstrates that TPPs rely upon AWP whether it is referenced in the relevant contracts or not.³⁸ Fact discovery demonstrates that TPPs rely upon AWP whether it is referenced in the relevant contracts or not.³⁹ The Court has recognized this in its *Memorandum and Order* (see pp. 14-16, 60-61); Dr. Berndt has recognized this in his February 9, 2005 Report (see ¶¶ 65 and 91-95 for Medicare).

VII. The Use of J-Codes by Commercial Payors Does Not Interfere with Accurate Calculation of Aggregate Class-Wide Damages

38. The use of J-Codes for invoicing payors for physician-administered drugs can be readily accommodated by my formulaic damage methodology, as I demonstrate below.

39. As discussed in my ¶ 16 above, both Judge Saris and Dr. Berndt⁴⁰ have noted that the use of J-Codes for invoicing physician-administered drugs under medical benefit claims has obfuscated the reimbursement process; made drug prices much less

³⁷ Although for Sub-Class 3, reference to AWP is required by Judge Saris (at p. 74) for multi-source drugs: “In the context of generic physician administered drugs reimbursed through private TPPs, ... generics will be considered only to the extent that the price in the contract between the TPP and physician is expressly predicated on AWP.”

Given the Court’s concern for this issue for Sub-Class 3, I exclude any damage calculations for multi-source drugs for Sub-Class 3. See Section IX below.

³⁸ MedPAC Report, June 2003, Chapter 9.

³⁹ See footnote 29 of my December 16, 2004 Rebuttal Declaration; ¶¶ 3-8 of my March 9, 2005 Rebuttal Declaration to Mr. Young’s Sur-Reply; and Attachment C to this Declaration.

⁴⁰ In his Report, Dr. Berndt concludes at p. 45, “In the market environment for physician-administered drugs, a variety of forces -- the relatively small dollar amounts they involve, the ambiguity of whether the claims stem from the medical or drug component of the health benefit, the troublesome relationships with providers who act as both buyers and sellers (and prescribers and dispensers) of physician-administered drugs, and the J-code claims system that has obfuscated the utilization and pricing of individual drug products and confounded close monitoring -- have together contributed instead to a system lacking checks and balances and inviting abuse. Some of that abuse has already been uncovered in this Court and elsewhere.”

transparent and difficult to monitor; and has created “opportunities for mischief and abuse” which have been the impetus for this litigation and have resulted “in the egregious examples of fraudulent pricing and marketing involving sales of Lupron and Zoladex to physicians.”⁴¹

40. This Court has articulated concern that the complexity of the J-Code system, which arguably has facilitated the AWP pricing scheme, may simultaneously make it difficult or impossible to accurately calculate the economic injury in the form of damages resulting from the scheme.⁴²

41. While it would be unfortunate indeed that one of the devices by which Defendants effectuated their fraudulent pricing scheme and thereby injured consumers would ultimately be the device behind which Defendants could hide from prosecution and payment of compensable damages for that injury, the situation is neither as dire as Mr. Young asserts⁴³ nor as uncertain as Dr. Berndt suggests.⁴⁴

⁴¹ At pp. 45-46 of Dr. Berndt's Report.

⁴² Specifically, the Court has stated (at pp. 69-70)

“The independent expert, Berndt, expresses concern with Hartman's analysis because of the poor quality of the data available. He cites ‘accounting ambiguities’ concerning whether physician-administered drugs were covered as medical or drug benefits and a J-Code classification system that ‘obfuscated true transaction prices and utilization’ in concluding that ‘the quality of general information concerning actual prices for physician-administered services is likely to have been very poor.’ (Berndt ¶ 228.) He also points out that the ‘high touch, high cost’ characteristics of physician administered drugs imply that the statistical variance from any sample of information could be ‘very high.’ (Berndt ¶ 229.) To exacerbate the difficulties in deciphering the data, the literature in the public domain is not helpful in the area of generic drugs administered by physicians. (Berndt ¶ 229.) In a follow-up memorandum, Dr. Berndt states that he expects that the cross-walking between the five-digit J-Code and the eleven-digit NDC code that will be necessary to track actual physician administered drug utilization and unit prices ‘is more likely to be feasible and reliable for the more recently introduced and typically more expensive biotech physician-administered drugs, and much less likely to be feasible and reliable for older, and in particular, multi-source off-patent and generic products.’ (Berndt Mem. of Aug. 9, 2005 at 2.) He adds that cross-walking will be less feasible for reimbursements made prior to 2000. (*Id.*)”

⁴³ At ¶ 142 of his Rebuttal Declaration, Mr. Young states “The [commercial payor] reimbursement data [for physician administered drugs] also show that a significant volume of transactions do not occur at a constant relationship to AWP. (See Exhibit 15)”

⁴⁴ At ¶ 197 of his Report, Dr. Berndt states, “This raises the issue of how easy and reliable it is to crosswalk from J-code to NDC-code claims. ... Just how labor intensive crosswalking will be, and how individualized the process will need to be in order to be reliable, particularly going back in time to the 1990s, is unclear to me at this point. This is an important issue that merits thoughtful and concise clarification by both Plaintiffs' and Defendants' experts.”

42. Let me summarize my opinions put forward to date in this matter regarding the methodological implications of the use of J-Codes or Q-Codes (which are simply HCPCS Codes):

- a) I have discussed and demonstrated in ¶¶ 29-31 and 34.c) of my December 16, 2004 Rebuttal Declaration that Dr. Gaier's and Mr. Young's presentations of all reimbursement rates within J-Codes (or Q-Codes) for specific commercial payors for particular physician-administered drugs grossly exaggerates the apparent dispersion of reimbursements rates by drug because both experts ignore the issue of multiple NDCs within each J- or Q-Code.⁴⁵ As I demonstrate even more fully below, this analytical flaw leads to their distorted interpretations and incorrect assertions regarding the ability to formulaically relate the AWP pricing scheme to the AWP of the individual NDCs of the particular drugs being reimbursed.
 - b) In ¶¶ 8-17 of my March 9, 2005 Rebuttal Declaration to Mr. Young's Sur-Reply Declaration, I again discuss and demonstrate that the reliance upon J-or Q-Codes by CMS and commercial payors does not alter the fact that claims for drug reimbursement are based upon the AWP of the individual NDCs or the AWP of the fundamental billing unit for that drug for that J-Code, and as a result, damages can be calculated by the formulaic methodology that I originally put forward in my September 3, 2004 Declaration in Support of Class Certification. In ¶¶ 19-26 of my March 9, 2005 Rebuttal Declaration, I explicitly addressed how my proposed formulaic methodology can be adapted to the calculation of damages for commercial payors reimbursing under J- or Q-Codes.
 - c) Based upon these analyses, I concluded (as quoted by Dr. Berndt in his ¶ 196) "the analyses by these experts [Dr. Gaier and Mr. Young] of physician-administered drugs for J-Codes with multiple NDCs are of little or no evidentiary value."
 - d) I maintain that opinion.
43. Since the source of the J- or Q-Codes for physician-administered drugs is the CMS, it is useful to review a recent Medicare Claims Processing Manual, specifically that chapter relevant to claims calculation and submission (Chapter 17), keeping in mind that reimbursement practices have changed over time. Portions of Chapter 17 are presented in Attachment D. Under Chapter 17 "Crosswalk to Old Manuals," Section 10 "Payment Rules for Drugs and Biologicals" it states

- a) "Most drugs furnished to hospital outpatients are packaged under the outpatient prospective payment system (OPPS). Their costs are recognized and included but

⁴⁵ In their analyses, they examine claims data for Taxol, Procrit and Zoladex for Humana, Oxford, BCBSKC (of Kansas City) and BCBSTN (of Tennessee). In his Sur-Reply, Mr. Young adds Remicade reimbursements by BCBSTN.

paid as part of the ambulatory payment classification (APC) for the service with which they are billed. Certain drugs, however, are paid separately. These include chemotherapeutic agents and the supportive and adjunctive drugs used with them, immunosuppressive drugs, orphan drugs, radiopharmaceuticals, and certain other drugs such as those given in the emergency room for heart attacks. The classes of drugs required to have 'pass through' payments made under the Balanced Budget Refinement Act of 1999 (BBRA) have coinsurance amounts that can be less than 20 percent of the Average Wholesale Price (AWP). This is because pass-through amounts, by law, are not subject to coinsurance. The CMS considers the amount of the payment rate that exceeds the estimated acquisition cost of the drug to be the pass-through amount. Thus, the coinsurance is based on a portion of the payment rate, not the full payment rate."

- b) "If the dosage given is not a multiple of the Health Insurance Common Procedure Coding System (HCPCS) code [that is, a J-or Q-Code], the provider rounds to the next highest unit in the HCPCS description for the code. If the full dosage provided is less than the dosage for the code specifying the minimum dosage for the drug, the provider reports the code for the minimum dosage amount." In Section 20.2, those drugs reimbursed under a HCPCS or J Code are to be filed using "the unit of measure by which such HCPCS code is defined" which has been called the "Fundamental Billing Unit."⁴⁶ In Section 20.5.4, "Find the Strength and Dosage," methods to identify and use the "fundamental billing unit" are provided.
- c) "Drugs and biologicals not paid on cost or prospective payment basis have been paid based on the lower of the billed charge or 95 percent of the average wholesale price (AWP) as reflected in published sources (e.g., RedBook, Price Alert, etc.). Examples of drugs that have been paid on this basis include but are not limited to drugs furnished incident to a physician's service, immunosuppressive drugs furnished by pharmacies, drugs furnished by pharmacies under the durable medical equipment benefit, covered oral anticancer drugs, and blood clotting factors. The Medicare Prescription Drug, Improvement, and Modernization Act (MPDIMA) of 2003 changed the basis for payment of drugs and biologicals not paid on a cost or prospective payment basis. Beginning January 1, 2004, through December 31, 2004, such drugs or biologicals are paid based on various standards specified in the statute, although the default standard is 85 percent of AWP."⁴⁷ In Section 20.2, those drugs for which reimbursement claims are submitted and paid that do not rely upon the "fundamental billing unit" are included in the Not otherwise classified (NOC) Drug Pricing File, for which CMS furnishes a NOC SDP file which contains the NDC code and drug name for every NOC drug under the HCPCS Code (J-Code) for which claims are submitted to local carriers; the unit of measure by which such drug is covered; and the Medicare allowed amount.

⁴⁶ See footnote 59 and ¶¶ 30-31 of my December 16, 2004 Rebuttal Declaration.

⁴⁷ There is some greater refinement of percentages off AWP for certain drugs, but the relationship is always sets by the Reference Manual and by statute; see Section 20 of chapter 17 in Attachment D. See also footnote 13 above.

- d) According to Section 20.4, "Calculation of AWP", "Carriers must ensure that if any NDCs are added or deleted, the formulae are applied appropriately. A separate AWP is calculated for each drug as defined by a HCPCS code. Within each HCPCS code there may be a single source or there may be many sources ..."

44. The implications of these statutory codifications for my damage analysis are the following.

- a) Some amount of total units of each of the 27 drugs in Table 2 that are subject to this litigation were dispensed through the hospital out-patient setting during some portion of the Class Period and the coinsurance amounts for those drugs were submitted as reimbursement claims (under Medicare reimbursement practices discussed in ¶ 43.a) above) to Class members. Some portion (20%) of this coinsurance (which should be billed as the actual acquisition cost) would be counted and included as damages.

Note, however, the following:

- I exclude from Class damages **all units sold to hospitals**, even if some of those units are dispensed in an out-patient setting and reimbursed in part by Class members. This exclusion applies to those units with coinsurance amounts. Hence, my aggregate damages calculations therefore will be conservative for the affected Sub-Classes.
 - Reimbursements for these coinsurance amounts would appear in commercial payor claims data as relatively unpredictable and perhaps seemingly random amounts. It is likely that many of such claims appear in the reimbursement claims data of the commercial payors put forward by Dr. Gaier and Mr. Young in their Rebuttal Declarations, which introduce considerable variation irrelevant to my calculation of damages.
 - Since I exclude these units from the total units subject to my damage analysis, these types of claims are also excluded from the analysis and any analytic difficulties introduced are eliminated.
- b) The majority of the remaining claims are determined by the AWP of the NDC administered or the AWP of the multiples of the fundamental unit administered.
- c) When commercial payors are reimbursing as secondary Medicare payors, those reimbursement claims will be 20% of some proportion of AWP (100%, 95% or 85%, depending upon the relevant year of the Class Period). The presence of such claims in commercial payor claims data bases introduces dispersion in the analyses of Dr. Gaier and Mr. Young, which they spuriously interpret as suggesting that claims are unrelated to AWP.

45. I agree with Dr. Berndt's statement in his August 9, 2005 Memorandum to Judge Saris: "Whether the crosswalking will be sufficiently reliable and comprehensive in the class certification context remains I think an open empirical issue." In approaching this

empirically, I focus on the period prior to 2000, precisely because that time period is mentioned to be of concern (see footnotes 42 and 44 above).

While I have not received all commercial payor data that I had requested, I have been able to make use of commercial payor data provided by Defendants' experts. For example, I have taken the claims data from one such payor, BCBS KC, and examined the amounts allowed (AA) for reimbursement on claims for one physician-administered drug for each of the five Track One Defendants. I present the results of my analysis in Table 4. I note the following.

- a) The allowed amounts found in the claims data for 1998⁴⁸ are either:
- An identifiable percentage of AWP, clearly well within the range found by the 2003 MedPAC Report, Table 9.2.
 - Unclearly related to AWP (designated as "unclear"). I interpret these claims to reflect coinsurance amounts on hospital out-patient administration (§ 43.a) above) for the most part, which I exclude from my analysis and damage calculations.
 - For four of the five drugs, allowed amounts are integer multiples of 90-105% of AWP,⁴⁹ indicating that the commercial payor reimbursed a total dollar amount related to an improperly reported quantity of units. Damages on such claims would be attributable to the entire allowed amount, regardless of the units reported.
 - Some percentage of each of the five drugs reported allowed amounts that were zero (\$0.00). The explanations possible for this finding are the following:
 - A claim was submitted by a provider with incomplete billing/diagnosis information and the amount allowed was \$0.00. The claim bounced back to the provider; the provider corrected the mistaken information; the claim was resubmitted and paid. In this case, this original claim and the observed allowed amount do not reflect a real reimbursement and are irrelevant, albeit they introduce spurious variation in the claims data base.
 - A claim was submitted by a provider with complete and correct information and was indeed rejected; that is, the amount allowed was \$0.00. In this case, the insured (who is part of one of the relevant Sub-

⁴⁸ For Remicade, the earliest year for which claims were available was 2000. The reasons are stated in Table 4.

⁴⁹ Specifically, the percentages of claims by drug are Zoladex (0%), Taxol (9%), Zofran (9%), Remicade (14%), and Intron A (36%).

Note that this range is conservative, since MedPAC finds that the range across payors is 85% to 115%. If I expanded the range here, the number of "unclear" claims would be reduced even further.

Classes) pays the claim and the damages are borne by that coinsurance payor (as calculated in Section IX below). Alternatively, the provider is not reimbursed and the claim remains unpaid. I have found no evidence suggesting that this situation occurs to any measurable extent.

- b) Based upon these data, I find no evidence to defeat the conclusion that substantially all claims for which allowed amounts are reimbursed will be included in my aggregate damage calculation. **Those claims that reflect reimbursements for coinsurance for hospital out-patient administration (i.e., “% unclear”) will not be included in the units subject to the aggregate damages calculation. The number of units subject to the damage analysis but for which reimbursement is actually not paid by some Sub-Class member (“zero dollar amount”) is small.**

46. The analysis in Table 4, which focuses upon the variation of allowed amounts for a single year (1998) for BCBS KC for the five drugs can be extended even further into the past. I do so in Attachments E.1 and E.2, for one of the drugs in Table 4, Zoladex. I do so using claims data submitted by Defendants’ experts for BCBS KC. I do so graphically. I note the following.

- a) Dr. Berndt has proffered the opinion (see footnotes 42 and 44 above) that the crosswalk between J-Codes and NDCs will more likely be feasible for more recently introduced drugs and less likely to be feasible for older drugs, particularly those dispensed and claimed prior to 2000.
- b) However, as made clear in Table 4, the crosswalk is certainly feasible for 1998. I can relate the amounts allowed by J-Code in 1998 to AWP for all or substantially all claims that are relevant to the damage analysis for each Track One Defendant.
- c) Furthermore, in Attachment E.1 and E.2, the dispersion and variation in reimbursements for Zoladex in 1998 are certainly less than in those years after 2000; that is, in those years in which the CMS HCPCS crosswalks were more formally codified and in which Dr. Berndt believes the crosswalks are more reliable.
- d) Attachment E.1 summarizes all claims data for BCBS of KC for J-Code 9092 (Zoladex). Note the following:
 - The dispersion over all claims is substantial.
 - However, the dispersion diminishes going backward from 2004 to 1995.
 - The dispersion includes many claims that are zero, which should be excluded as discussed above. The dispersion includes many claims that are multiples of distinct percentages of AWP.

Table 4: Blue Cross Blue Shield of Kansas City

1998 Medical Claims Data

Drug name	Distribution of Allowed Amounts
Zoladex (AZ) J-Code examined = J9202	12%: zero dollar amount 27%: 94% of AWP 44%: 95% of AWP 9%: 100% of AWP 8%: Unclear
Taxol (BMS) J-Code examined = J9265	19%: zero dollar amount 16%: 95% of AWP (FDB) 40%: 100% of AWP (FDB) 9%: 104% of AWP (FDB); 100% of AWP RedBook 9%: appear to have errors in units; that is, allowed amounts were integer multiples of 90% to 105% of AWP. 8%: Unclear
Zofran (GSK) J-Code examined = J2405	11%: zero dollar amount 15%: 95% of AWP 47%: 98% of AWP 2%: 100% of AWP 5%: 105/6% of AWP 9%: Appear to have errors in units; that is, allowed amounts were integer multiples of 90% to 105% of AWP. 11%: Unclear
Remicade (JJ) J-Code examined = J1745 Note: Because Remicade claims begin to appear in January 2000, calendar year 2000 was used rather than 1998.	36%: zero dollar amount 37%: 90% of AWP 7%: 95% of AWP 2%: 100% of AWP 14%: Appear to have errors in units; that is, allowed amounts were integer multiples of 90% or 105% of AWP. 4%: Unclear
Intron A (SP) J-Code examined = J9214	7%: zero dollar amount 17%: 95% of AWP 11%: 100% of AWP 24%: 103% of AWP 36%: Appear to have errors in units; that is, allowed amounts were integer multiples of 95% or 100% of AWP. 5%: Unclear

- Using Table 4, when I eliminate the claims for zero reimbursement and I correct the claims for the integer multiples of a standard percentage range of AWP (90-105%), I obtain Attachment E.2.
 - In Attachment E.2, the overall variation is diminished considerably. At the same time, the identical pattern of diminishing variation going backward from 2004 to 1995 remains.
- e) In both cases, I find that the variation and dispersion in reimbursements in 1994-1997 was even less than in 1998 and was substantially less than it was during the period 2000-2004.
- f) Hence, I find nothing in these claims data that suggest that BCBS KC was unable to relate (and reimburse) submitted claims to the AWP of the relevant NDC in 1998 specifically and prior to 2000 generally.

47. In ¶ 14 of my March 9, 2005 Rebuttal Declaration to the Sur-Reply Declaration of Mr. Young, I introduced and discussed evidentiary materials including contracts and letters between commercial payors and providers, deposition testimony of representatives of commercial payors, and deposition testimony and discovery materials for Defendant manufacturers. These materials demonstrate reliance by commercial payors upon AWP for the fundamental billing unit or for the actual NDCs. Such reliance would produce results analogous to those found in Table 4 above.

In addition, I have asked Counsel to summarize contracts that have been found in Mr. Young's supporting materials. That summary has already been introduced in Attachment C to this Declaration. The specific J-Code mentioned in the contracts in Attachment C is Q0136, which is for Procrit (J&J). There are 14 NDCs listed in the recent CMS crosswalk (8 if one counts only the first nine digits) for Procrit/Q0136.⁵⁰ The other class of drugs singled out in the contracts is chemotherapy drugs. Temodar, doxorubicin (Rubex), bleomycin, carboplatin, Paraplatin, cisplatin, Cytosan, Etoposide/Vepesid, and paclitaxel are all examples of chemotherapy drugs with multiple NDCs per J-Code. Albuterol is another drug I have examined that has many NDCs per J-Code. The contracts almost always refer reimbursement to the AWP (rather than the AWP of the fundamental billing unit), which by implication applies to the AWP of the specific NDC of the drug administered as part of the medical service. Hence, these

⁵⁰ For the most recent crosswalk, see <http://www.cms.hhs.gov/providers/drugs/asp.asp>.

contracts either rely upon J-Codes and the relevant AWP by NDC or they rely upon AWP by NDC specifically. Hence, no cross-walk is required.

Clearly, the most recent CMS crosswalks are comprehensive and allow for a detailed description and quantification of the relationship between J-Codes and the related multiple NDCs and their respective AWP. However, the information that has been published in these recent crosswalks were being gathered over the years since 2000⁵¹ and have consistently improved commercial payors ability to cross-walk and relate reimbursement claims to the NDCs/AWPs of the physician-administered drugs involved in the related medical procedures. Finally, the analyses that I have presented in Table 4 and Attachment E demonstrate that commercial payors could readily distinguish the relevant NDCs and AWP for determination of the amount allowed for a physician-administered drug for a given medical benefit before 2000.

48. Finally, and importantly, the feasibility of crosswalking J-Codes to NDCs has been examined and successfully implemented by the OIG much earlier than 2000. For example, in a May 1996 publication analyzing the appropriateness of 1994 Medicare prescription drug allowances,⁵² the OIG undertook an analysis which found the following:

- “Medicare presently pays for most prescription drugs based on the Average Wholesale Price of the drug products” (p. ii).
- “Drugs are billed to the Medicare program based on codes developed by HCFA. These codes are developed as part of the HCFA Common Procedure Coding System (HCPCS). The codes define the type of drug and, in most cases, a dosage amount. The codes do not indicate whether a brand or generic version of the drug was administered” (p. ii).⁵³

⁵¹ As stated by the CMS in its February 7, 2003 Program Memorandum [to] Carriers, “On August 17, 2000, we published a final rule (65 FR 50311) that implements standards for electronic transactions in accordance with the administrative simplification provisions of HIPAA. This rule became effective on October 16, 2000. HIPAA required Medicare and other insurers to be capable of processing claims using NDCs for drugs within 24 months (by no later than October 1, 2002) after the effective date of the final rule. A subsequent law, the Administrative Simplification Compliance Act (ASCA) of December 2001, allowed covered entities to request an extension until October 16, 2003 for implementation.”

⁵² Department of Health and Human Services, Office of Inspector General, “Appropriateness of Medicare Prescription Drug Allowances, May, 1996, OEI-03-95-00420.

⁵³ “Most drugs suppliers bill Medicaid for reimbursement using a national drug code (NDC), ... from [which] the drug can be identified as a brand or generic version” (p. 2).

- “The drug code list [that was analyzed] primarily contained HCPCS codes beginning with a J (known as J codes) which represent mainly injectable drugs or drugs used in conjunction with durable medical equipment. Also included in our list of drugs were K codes which usually represent immunosuppressive drugs, Q codes which represent mainly drugs used for End Stage Renal Disease, several A codes that represent drugs used diagnostic imaging” (p. 3).
- [In the analysis,] “We needed to link Medicare’s HCPCS codes to NDC codes. This involved matching the drug product and dosage defined by the HCPCS code with the corresponding NDC codes for all available brand and generic versions of the drug” (p. 3). The analysis focused upon 17 HCPCS codes.
- “For 10 of the 17 codes, the process of linking the HCPCS code with corresponding NDC codes was relatively easy to accomplish since the HCPCS codes represented single-source drugs where only one brand name drug was available. For these drugs, we collected NDC codes that matched the drug dosage requirements outlined in the HCPCS descriptions” (p. 4).
- “For the remaining seven drug codes, we needed to determine all of the versions (both brand and generic) of the drugs produced by different manufacturers that met the HCPCS dosage requirement” (p. 4).

I conclude that the crosswalk from HCPCS Codes to NDC codes was considered “relatively easy” for single-source drugs as early as 1994. For multi-source drugs, the crosswalk was more data intensive but still possible.⁵⁴ It involved identifying all versions, including generic and branded, of the drugs meeting the HCPCS dosage requirement. I know that a crosswalk is possible, because I have implemented one in my damage calculations as discussed in Section IX below.

49. I conclude that for all or substantially all of the J-Codes relevant to this analysis, there are multiple NDCs. I conclude from the contracts, discovery materials and publicly available information I have reviewed that for all NDCs within all J-Codes relevant to the Sub-Classes, the provider has been contractually required to and did submit a claim for reimbursement for some percentage of AWP, unless the provider were a hospital outpatient facility billing the coinsurance amount. I conclude that commercial payors were able to distinguish the amount allowed on the relevant medical benefit claim and paid an allowed amount that related to the AWP of the relevant NDC or of the

⁵⁴ 15 of the 27 drugs analyzed in this litigation were single source throughout the Damage Period; of the remaining 12, 6 were single-source for a substantial portion of the Damage Period. The six drugs that went multi-source by 1994 are the following: Rubex (in 1990); Ventolin (in 1992); generic albuterol sulfate (in 1992); Proventil (in 1992); generic perphenazine (in 1993); and Vepesid (in 1994).

fundamental billing unit for the J-Code for all drugs relevant to the Sub-Classes. In some cases, the allowed amount was equal to integer multiples of some percentage of AWP, indicating that the allowed amount reflected $x\% \times \text{AWP} \times \text{number of units}$. Damage calculations for such multiple unit claims are straightforward, as discussed below (Section IX). When reimbursement was paid for coinsurance on an out-patient administration, I do not include those units in my damage analysis.⁵⁵

VIII. Liability Analysis

A. Overview of the Alleged Fraudulent Pricing Practices

50. In ¶¶ 12-19 and in Attachment E of my September 3, 2004 Declaration I identified the incentives faced by drug manufacturers to engage in the AWP pricing scheme to move market share of specific drugs. I discussed why prices in the market were sufficiently non-transparent to make it difficult to monitor and thereby defeat such a scheme. I discussed how the markets in which certain providers operated were sufficiently non-competitive to allow them to profit from the scheme (see Attachments C and D to my September 3, 2004 Declaration).

51. The Court has recognized (at pp. 29-31 of the *Memorandum and Order*) these incentives for the scheme and the structural reasons why the scheme could succeed, at least for physician-administered drugs, as cited in my ¶ 16 above.

52. The independent expert to the Court, Dr. Berndt, has further acknowledged (at his p. 46) the specific “egregious examples of fraudulent pricing and marketing involving sales of Lupron and Zoladex to physicians.”

⁵⁵ Parenthetically, I further conclude that when there are multiple NDCs for a J-Code and when coinsurance on hospital out-patient amounts, zero amounts and MediGap-type amounts for the 20% Medicare co-insurance are included, of course there will be a large variation in reported reimbursement rates many of which will appear to be unrelated to the AWP for a single NDC. This is precisely the problem inherent in the analyses of Mr. Young and Dr. Gaier, as I explicitly pointed out in my December 16, 2004 Rebuttal Declaration (¶¶ 29-31 and 34.c) and in my March 9, 2005 Rebuttal Declaration to Mr. Young’s Sur-Reply (¶¶ 9-17). For the reasons presented in this Section, I conclude, as before, that their presentations are spurious and misleading.

53. Reports to Congress have identified identical motivations and behavior in the Zoladex and Lupron litigation and for other chemotherapy drugs. For example, the MedPAC Report states (at pp. 155-158; emphases added in **bold**):

- a) "In percentage terms, the biggest difference between the listed AWP for drugs and actual prices paid by physicians and suppliers tends to occur with generic drugs or brand name drugs for which there are alternatives available in the same therapeutic class. **For these drugs, manufacturers compete to increase their market share.** This competition can take two forms. **A manufacturer may raise the AWP for its product without changing the price charged to purchasers.** Although the manufacturer's profit per dose will not increase with the rise in the listed price, **the bigger difference between providers' acquisition costs and Medicare payment leads to higher profits for providers when they choose the manufacturer's product over its competitor.** At the same time, coinsurance payments charged to beneficiaries will rise as the AWP increases. A hearing before the House Energy and Commerce Subcommittee on Health highlighted this outcome on September 21, 2001. One chemotherapy drug, Vincasar, which had an AWP of \$740, was sold to physicians for \$7.50 per dose. The beneficiary's copayment (about \$150) was about 20 times providers' acquisition cost. Possibly in response to increasing scrutiny of drug pricing practices by the courts, **some manufacturers have adopted an alternative marketing strategy. They leave the AWP's at existing levels, and offer larger discounts directly to physicians who choose their drugs over products offered by competitors. In this case, the manufacturers' profit per unit dose will be less, but overall profits increase if the discounts result in increased market share.** On May 5, 2003, the Office of Inspector General (2003) issued voluntary compliance guidelines for pharmaceutical manufacturers. If a manufacturer manipulates the AWP to increase federal payments to its customers, the federal antikickback statute is implicated. In other words, it is illegal for a manufacturer knowingly to establish or maintain an AWP if one purpose is to manipulate the spread to induce customers to purchase its products."
- b) "In October 2001, TAP Pharmaceutical Products, Inc. pleaded guilty to conspiring to violate the Prescription Drug Marketing Act. The central issue in the case was the allegation that TAP had encouraged urologists to bill Medicare for free samples provided by the company. TAP markets Lupron ..., a treatment for prostate cancer. Lupron competes with another drug called Zolodex In 2001, expenditures for Lupron and Zoladex were, respectively, the second and fourth highest of all drugs covered under Part B. Payments based on the easily manipulated average wholesale price (AWP) have allowed marketing abuses by manufacturers of these drugs. In the civil suit, the government alleged that the company had set AWP's far above the price that any of its customers paid and encouraged physicians to take advantage of the difference by billing Medicare for the AWP minus 5 percent. As part of its settlement with the federal government, TAP agreed to pay \$875 million dollars to resolve criminal and civil liabilities in connection with its pricing and marketing of Lupron. More than a dozen former

TAP employees are still under indictment for using kickbacks and bribes to get doctors to use Lupron rather than Zolodex. This litigation also has led to further lawsuits by the Attorneys General in many states. These as yet unresolved suits focus on the discrepancy between AWP's and the actual acquisition prices available to retailers. Similar charges have been filed against the makers of Zolodex. One physician pleaded guilty to billing Medicare for between \$30,000 and \$70,000 for free samples he received from the manufacturer (Bureau of National Affairs 2002)."

54. Fact discovery corroborates liability. I identify discovery supporting this finding in Attachment F to this Declaration. Among other materials, Attachment F includes quotes and pricing data from the manufacturers of Zofran and Kytril and quotes and pricing data from the manufacturer of Zoladex.

55. Finally, the December 15, 2005 Declaration of Dr. Meredith Rosenthal⁵⁶ discusses the fraudulent use of the AWP scheme by selected Track One Defendants and for specific Track One drugs.

B. The Procedure to Determine the Causation and Liability

56. The basis for my finding of causation and liability is empirical. It requires a comparison of actual spreads with yardstick spreads. I conduct my analysis for the drugs listed in Table 2 by calculating the ASPs by NDC for each drug as precisely as the manufacturer data production allows. These ASPs are presented in Attachment G. Given those ASPs, I identify the relevant AWP's, which are also presented in Attachment G.⁵⁷ Using the AWP and ASP, I calculate the spread for drug *j* of Defendant *k* as $\text{Spread}_{jk} = (\text{AWP}_{jk} - \text{ASP}_{jk}) / \text{ASP}_{jk}$. These spreads are presented in Attachment G.⁵⁸

⁵⁶ "Liability Report of Dr. Meredith Rosenthal," *In re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, United States District Court for the District of Massachusetts, December 15, 2005.

⁵⁷ I use RedBook throughout for my AWP's, unless such data were unavailable. In that case, I relied upon First DataBank. I note that the discovery materials suggest that Medicare carriers frequently make use of RedBook for their AWP's. It is possible that some of the payor claims data make use of First DataBank, the AWP's of which at times diverge somewhat from those found in RedBook.

⁵⁸ The information in Attachment G is presented as follows. Each Table G.1-G.5 is designated for each of the five Track One Defendants in the following respective order: AstraZeneca (AZ), Bristol-Myers (BMS), GlaxoSmithKline (GSK), Johnson & Johnson (J&J) and Schering-Plough (SP). For each firm, the data are presented as follows: Table G.1.a contains the ASPs; Table G.1.b contains the AWP's; Table G.1.c contains the spreads; and Table G.1.d contains all supporting documentation for the data and the data analysis.

Since it is necessary for a manufacturer to increase the spread of the relevant physician-administered drug above what would have been the case absent the fraud in order to implement and benefit from the AWP scheme, I find causation and liability for any NDC of any of these drugs if Equation (1a) of my September 3, 2004 Declaration is found to hold. Specifically the alleged AWP scheme excessively raised reimbursement rates for drug *j* of Defendant *k* if

$$(1a) \quad \text{Spread}_{jk} > \text{Spread}_{jk}^{\text{but-for}}.$$

C. Yardsticks for a Finding of Causation and Liability

57. Equation (1a) explicitly relies upon the notion of the yardsticks that I discussed in my earlier Declarations and that the Court has recognized at p. 63 of the *Memorandum and Order*.

58. As noted above, the alleged AWP scheme was effectuated when a manufacturer increased the AWP of the drug and/or decreased its ASP in order to offer financial incentives to providers to move market share. Reliance upon increased, non-transparent and unmonitored spreads became strategically useful to drug manufacturers when they faced increased therapeutic competition. In the absence of therapeutic competition, a given manufacturer would find it unnecessary **and unprofitable (if ASP were reduced)** to increase spreads to move market share. Hence, as noted with my discussion of Table 3 above, successful “break-through” innovator drugs serve as reasonable yardsticks for “but-for” spreads, specifically, for spreads that would be anticipated in the market when spread manipulation was unnecessary to move market share and was therefore not undertaken.

59. While I have requested of Defendants data for as many drugs in Tables 3.A and 3.B as possible, I have received limited usable data. I have, however, been able to make use of some Defendant data, data and analyses of Defendants’ experts, and other data. I will continue to examine data I have requested of Counsel and will refine my yardsticks as such data are made available.

a) Specific physician-administered drugs

- In Attachment H.1, I present AWP and ASP information for Zofran (see Table 3.B). The data for Zofran NDC 00173044200 are compelling. Zofran launched as the first Serotonin 5-HT₃ Blocker (antiemetic), a unique market niche. It did not face therapeutic competition until Kytril launched in 1994. Once Kytril did launch, the manufacturers of each drug clearly used spread (see Attachment F of this Declaration) to compete for market share, as alleged and as described in Attachment E of my September 3, 2004 Declaration. Prior to the time that GSK felt compelled to increase spread to move market share in 1994, its spread was 18.6%-20% for the three years, 1991-1993. Once therapeutic competition arose, the spreads were increased to compete for market share, as described in Attachment F to this Declaration.⁵⁹
 - In Attachment H.2, I present the AWP and ASPs for Taxol from its launch in 1993. At that time, it was the only therapeutic competitor offering Paclitaxel. When it launched, using RedBook AWP, its spread was 25% and remained at 25-27% from 1994 until 2000, when generic launch introduced price competition to move market share. When it launched, using First DataBank AWP, its spread was 20% and remained at 21-22% from 1994 until 2000, when generic launch introduced price competition to move market share.
 - In Attachment H.3, I present the AWP and ASPs of Blenoxane, which was not included in Table 3.B. Using Red Book AWP, it launched in 1993 with a spread of about 27% and remained at that level until it faced competition motivating it to increase its spread. Using First DataBank AWP, it launched in 1993 with a spread of about 22% and remained at that level until it faced competition motivating it to increase its spread.
 - I conclude that the relevant yardsticks provided by innovator single-source physician-administered drugs untainted by the AWP inflation scheme and based upon Red Book AWP (in this case, Class drugs prior to the time they began to effectuate the AWP scheme) range from 18-27%. If I based my yardsticks upon First DataBank AWP, the range would be 18%-22%
- b) As cited in ¶ 22. b) above, in the course of my analysis for this matter I have reviewed a variety of publicly-available survey research summarizing the “market” expectations of spreads for single-source physician-administered drugs. For this group, the range of reasonably anticipated spreads found in the survey research is 11%-25%, which corroborates the comparator drugs introduced in ¶ 59.a) above.
- c) Dr. Gaier admits to a yardstick of 20-25% in his Rebuttal Declaration for all single-source innovator drugs.⁶⁰

⁵⁹ Note that Zofran’s AWP are equivalent in the RedBook and First DataBank. This is not the case for Taxol and Blenoxane.

⁶⁰ In the process Dr. Gaier reveals confusion regarding the coincidence of the proffered opinions of Dr. Schondelmeyer and me. Specifically, at his ¶ 58 Dr. Gaier states, “Notwithstanding the record evidence that many payors did not expect AWP was a signal for manufacturer’s selling price, Dr. Hartman’s assertion that payors were harmed because they incorrectly ‘expected that AWP is larger than ASP by a

- d) Reimbursement patterns for most physician-administered drugs, whether administered under Medicare coverage or under private commercial payor coverage, are driven primarily by Medicare reimbursement practices.⁶¹ As a result, contracts negotiated by commercial payors with provider groups offer less information about “revealed preferences” or “revealed expectations” about spreads than do TPP contracts with PBMs for single-source self-administered orals.⁶²
- e) Given the information available, I weight most heavily the evidence from the physician-administered comparator drugs and the publicly available survey research for physician-administered drugs. I conclude that a reasonable range of yardsticks for spreads untainted by the AWP scheme is 11%-25%, using First DataBank. However, using RedBook AWP, I conclude that a reasonable range of yardsticks for spreads untainted by the AWP scheme is 11%-27%. To be conservative, I choose 30% as my yardstick for a finding of liability. Specifically, if a manufacturer either raises its AWP and/or lowers its ASP such that the realized spread exceeds 30% for a given NDC for a given period of time (I choose a year), I conclude that the manufacturer has fraudulently increased the spread on that NDC in that period to move market share.
- f) It is appropriate to proceed by NDC and its related AWP. It is clear from discovery materials, fact evidence and my analysis in the Lupron matter that manufacturers decide to artificially increase the spread for a given NDC relative to other NDCs for strategic reasons. Indeed, I understand that there has been documentation of the temptation to shop NDCs for the highest AWP.

The fact evidence certainly indicates that manufacturers strategically increase and decrease the spreads of certain NDCs over time relative to other NDCs, as their marketing strategies and product life cycles evolve. Likewise, providers can reasonably be assumed to be profit-maximizing actors who bill the most they can

reasonably predictable amount’ is contradicted by plaintiffs’ expert, Dr. Schondelmeyer (Schondelmeyer Declaration, p. 37; *Emphasis added*), who writes:

‘For most brand name products that are still covered by patent or exclusivity terms, the price relationship between list prices (AWP and WAC) and actual transaction prices (actual acquisition cost or average selling price) for a given class of trade is *reasonably predictable*. That is, the WAC is equal to, or close to (+ or - 5%) the actual acquisition cost for the community pharmacy class of trade and the AWP, at present, is typically 20 to 25 percent above the WAC, or alternatively, WAC is 16.67 or 20 percent below AWP. *In such cases, a payment policy using AWP as a benchmark (e.g., usually AWP minus a certain percent) may be relatively accurate.*’”

Despite Dr. Gaier’s confused assertion to the contrary, there is no contradiction between Dr. Schondelmeyer and me. We are in complete agreement. We both agree that for single-source self-administered innovator drugs, the market *reasonably predicted* that AWP was approximately 20-25% above drug acquisition costs, or the ASP.

⁶¹ Again, See MedPAC Report, chapter 9.

⁶² Both Mr. Young and I agree that negotiated reimbursement rates are AWP minus 13%-18% for these drugs (*Memorandum and Order*, p. 64), which allows for the pharmacy margins discussed in Attachment K to this Declaration. For physician-administered drugs, contracted reimbursement rates are AWP \pm 15%.

for the drug administered. Providers will certainly not bill less than the allowed AWP for a particular NDC.

D. Conclusions of the Liability Analysis

60. Using this yardstick of 30%, I identify in Attachment I when any of the drugs (by NDC and year of liability) of each of the Track One Defendants (by Defendant in Tables I.1-I.5) exceed that threshold for liability. I find that drugs for all five Track One manufacturers do. I interpret my use of the liability yardstick of 30% as follows.

- a) Prescription and administration of a particular physician-administered drug is aptly characterized as “high touch” by Dr. Berndt (at his p. 53), which I take to mean “specialized to the case at hand.” Choice of the appropriate drug is not something commonly subjected to formulary review. As a result, there is little payor oversight; critical review of a provider’s choice of drug therapy and the price of the selected drug is most typically believed to be beyond the expertise of the TPP. The provider determines the drug being administered. The choice of drug is determined by the training of the provider and the provider’s specific knowledge of the patient, the patient’s clinical profile and the patient’s medical needs.
- b) Not only do TPPs feel medically inadequate to review physician/provider choice of therapy, TPPs correctly believe that such review is not cost-effective. As so aptly paraphrased by Dr. Berndt, “If spending on some good or service is perceived to be only a small portion of total costs, that good or service will not be as likely to be on cost cutters’ radar screens; instead, they will tend to focus more on big-ticket items.” As we know by now, Dr. Berndt calls this insight the “Importance of Being Unimportant,” and he infers that over the past 10 years managed care organizations and payors focused their cost cutting efforts and analyses on hospital care, physician services and “all other” categories of reimbursement and expenditure, **rather than** pharmaceutical reimbursements, which have been relatively less important. **This unimportance is even more important for physician-administered drugs**, which represent a small portion of an already small component of costs (i.e., the cost of all pharmaceuticals).
- c) In light of this situation, TPPs have looked for easily ascertainable rules of thumb or signals for expectations regarding reasonable claims for reimbursement of physician administered drugs. Since Medicare has taken the lead with such reimbursement under Part B, it is not surprising that TPPs follow Medicare’s lead. Reliance upon AWP has followed, as has the assumption that AWP provides a reasonable signal for ASP.
- d) Relevant market surveys and data for relevant comparator drugs indicate that single-source physician-administered drugs that did not manipulate spreads to capture market share exhibited spreads that ranged from 11-25% and centered around 20% using First DataBank; they ranged from 11-27% and centered around

20%-25% using Red Book. Such information would naturally inform the pricing expectations of all payors who had little independent information about the relevant price spreads.

- e) Over much of the last 20 years, many physician-administered drugs have been single-source (see *Memorandum and Order*, p. 29). Indeed, the majority of drugs subject to damages in this matter are single-source (see footnote 54 above), and almost all of the drugs are single-source for some portion of the Damage Period.
- f) There is no evidence that the yardsticks for TPP price expectations for multi-source physician-administered drugs were any different than those for single-source physician-administered drugs.⁶³ Indeed, in light of the preceding facts, there is no reason to expect that they would or could be. As a result, I use the same yardstick for liability for all physician-administered drugs, whether single-source or multi-source.
- g) Despite the fact that publicly-available information suggesting increasing spreads became more prevalent in the latter years of the Damage Period, TPPs were not able to act on such information for the reasons cited above.

IX. Damage Calculations

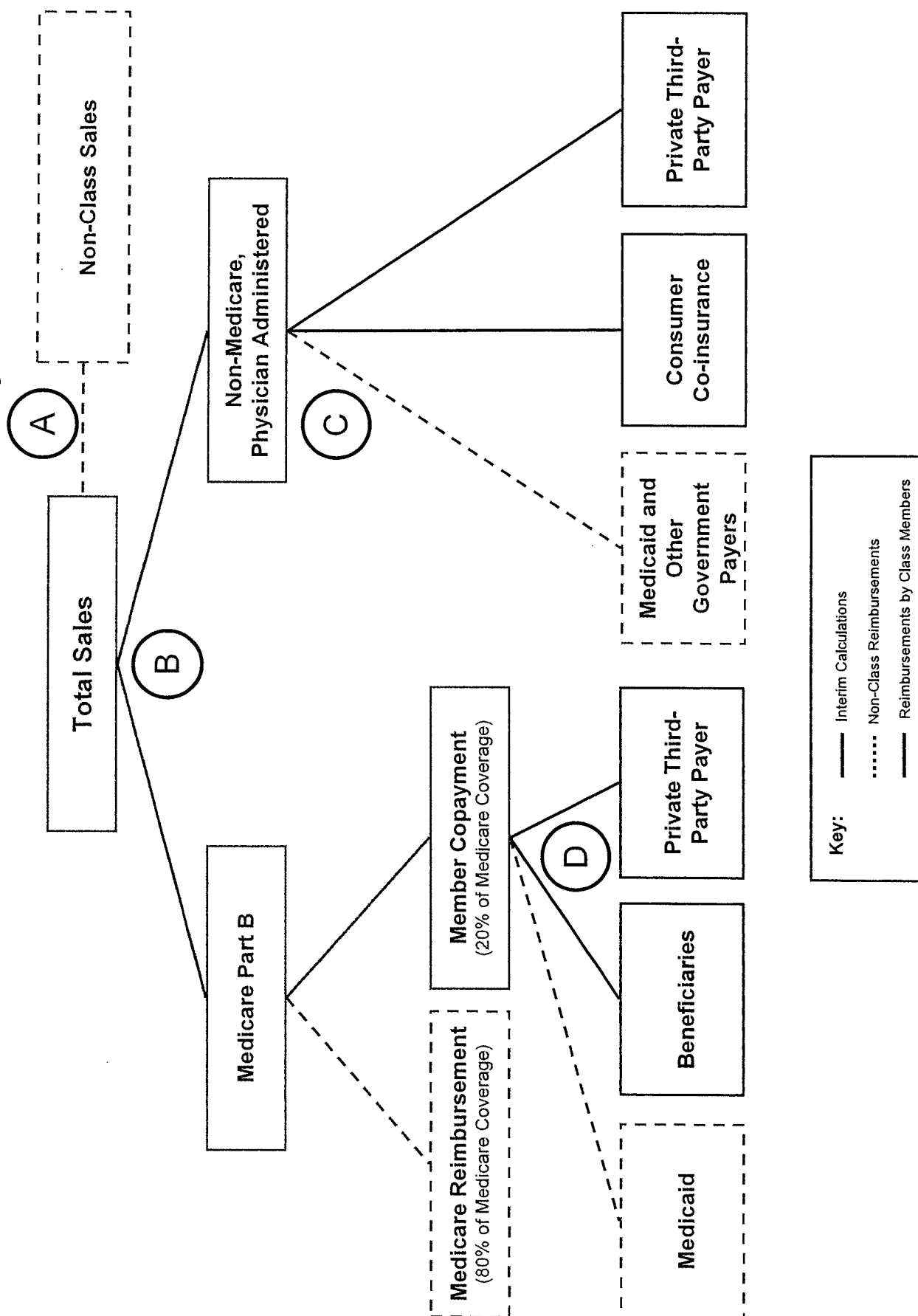
A. Overview of Damage Analysis

61. A schematic diagram of the flow of units to Medicare and non-Medicare payors subject to the damage analysis is presented in Figure 2. There are four important analytic nodes in the Figure, Node A through Node D.

At the start of my analysis of liability and damages, I integrate all sales, chargeback and rebate data (provided to date) for all physician-administered and Medicare Part B covered drugs from each of the five Track One Defendants. At the time of the submission of this Declaration, these data were not complete. I identify where data were not provided and how I accommodated the damage calculations appropriately in the notes to the relevant damage tables in Attachment J.

⁶³ There is no survey information of which I am aware that has documented spreads on generic physician-administered pharmaceuticals. Dr. Berndt agrees, stating at ¶ 229 “the literature in the public domain is not helpful in the area of generic drugs administered by physicians.” Given the even greater lack of pricing transparency for these drugs, relative to self-administered orals, there is no compelling reason that pricing expectations for generic physician-administered drugs would be more educated (i.e., different) than the observed relationship for single-source physician-administered drugs.

Figure 2: Schematic of Sales and Reimbursement by Sub-Class



Broadly speaking, I use the identifiers for customer name, type, and class of trade to exclude, at Node A, all direct units sold to such entities as hospitals, government entities, managed care dispensaries, and those units distributed through wholesalers which are not later distributed to the physician providers who in turn administer to the Class. Those units not excluded by this process are those distributed to physicians, physician groups, oncology groups, clinics, long-term care facilities, nursing homes and certain others. A more precise taxonomy is presented in the notes of Attachment G. When I exclude those units distributed to entities who are not providers to Sub-Class members, I also exclude the related chargebacks and rebates. As a result, the ASPs I present in Attachment G are based upon invoiced sales data, price offsets, chargebacks and rebates on units distributed solely to the Sub-Classes.

Having identified those units (and their ASPs) relevant to the Sub-Classes as a whole, I differentiate, at Node B, those units distributed through providers to Medicare Part B patients and those distributed to non-Medicare patients. This differentiation is currently being based (to the extent possible given data received to date) and will be based (at the time I receive IMS data requested of Defendants) on survey data summarizing method of payment for procedures at physicians' offices. The two major sources of these data are the National Ambulatory Medical Care Survey (NAMCS) data⁶⁴ and the IMS National Disease and Therapeutic Index (NDTI) data.⁶⁵ Having differentiated those units that are reimbursed by Medicare Part B as the primary insurer and those that are reimbursed by non-Medicare payors, I calculate, at Node C, the extent to which the non-Medicare reimbursements are borne as TPP reimbursements, as co-insurance payments and by other non-Class payors (e.g., Medicaid and other governmental entities, which are of course excluded from Sub-Class damages). At Node

⁶⁴ The National Ambulatory Medical Care Survey (NAMCS) is a widely-used public data set which provides information on the characteristics of the patients (including their insurance) and the providers that use drugs in ambulatory settings. The NAMCS is a national probability sample survey conducted by the Division of Health Care Statistics, National Center for Health Statistics (NCHS), and the Centers for Disease Control and Prevention (CDC). A national sample of office-based physicians provides data on patients' office visits. I have data for 1993-2003 for the drugs in this matter for which data are available.

⁶⁵ The IMS National Disease and Therapeutic Index (NDTI) Data is an office-based survey also summarizing for each physician-administered/Part B drug the method of payment (insurer), the scripts prescribed, the manufacturer, the form (e.g., injectible, tablets, etc.), and the strength (e.g. 15 mg, 30 mg, etc.). I have requested but have yet to receive these data from Defendants.

D, I calculate the portion of the 20% Medicare copay that is reimbursed by TPPs providing MediGap-type supplemental insurance and that portion paid by consumers. I also exclude the portion paid by Medicaid. At both Node C and D, I rely upon existing survey analyses of these payment patterns.⁶⁶

62. I implement my formulaic damage methodology for each manufacturer, as requested by the Court (see ¶ 6 above). However, my analysis demonstrates that implementation is identical for each Defendant.

B. Yardsticks for Calculating Damages

63. Having identified the drugs (by NDC and year) that have been subject to the AWP scheme (causation and liability by manufacturer, by NDC and by year), injury is calculated using the following yardsticks for damages.

a) Under Medicare Reimbursement for Sub-Classes 1 and 2

- For single-source Part B drugs:
 - For the period 1991-2003, I have identified the relevant yardstick in ¶ 19 above as $\text{Spread}_{jk}^{\text{but-for}} = 0.00$. Actual spreads, Spread_{jk} , relative to the ASP will be based upon AWP for 1991-1997 and $95\% \cdot \text{AWP}$ for 1998-2003.
 - For 2004, $\text{Spread}_{jk}^{\text{but-for}} = 30\%$, the liability yardstick. As discussed in ¶¶ 18-19 above, in 2004 reimbursement was set at $85\% \cdot \text{AWP}$,⁶⁷ and the reimbursement rate was artificially inflated by $85\% \cdot (\text{AWP} - \text{AWP}_{\text{but-for}})$. Note that a 25% yardstick sets $\text{AWP}_{\text{but-for}}$ at $125\% \cdot \text{ASP}$; and the but-for reimbursement rate therefore becomes $85\% \cdot 125\% \cdot \text{ASP} = 106.25\% \cdot \text{ASP}$, which is essentially the reimbursement rate allowed under the most recent revisions to the Medicare statutes (see the preceding footnote). The use of

⁶⁶ The sources and the exclusions are identified in the relevant tables. Besides Medicaid reimbursements, other exclusions reflect units distributed indirectly to Federal, state and local government employees, which are reimbursed by private TPPs. These exclusions are in addition to those excluded as direct government sales at Node A.

At each Node, where I have found supplemental anecdotal information, I judgmentally incorporate that information into the percentage disaggregations.

⁶⁷ As discussed in ¶¶ 18-20 & 43 and footnote 13 above and in Attachment D (Section 10) to this Declaration, the Medicare Prescription Drug Improvement and Modernization Act of 2003 based reimbursement on 85% (as a default percentage) of the AWP as of April 1, 2003; however, a range of the percentages running from 80%-95% is allowed. In the actual damage calculations reported here, I have identified the specific percentage of AWP allowed for each NDC.

my 30% yardstick is therefore conservative, allowing for an AWP higher than that reflected by the Amendments to Medicare.

- For multi-source Part B drugs:
 - For 1991, $\text{Spread}_{jk}^{\text{but-for}} = 0.00$ and the actual spread, Spread_{jk} , will be calculated using the AWP relative to the ASP.
 - For the period 1992-1997, $\text{Spread}_{jk}^{\text{but-for}} = 0.00$ and the actual spread, Spread_{jk} , will be calculated using the median AWP for all generics relative to the ASP.
 - For the period 1998-2003, $\text{Spread}_{jk}^{\text{but-for}} = 0.00$ and the actual spread, Spread_{jk} , will be calculated using 95% of the lesser of the median AWP for all generics or the lowest brand AWP relative to the ASP.
 - As with the single-source drugs, in 2004 the $\text{Spread}_{jk}^{\text{but-for}} = 30\%$, the liability yardstick. Likewise, reimbursement was set at $85\% \times \text{AWP}$ (see footnotes 13 and 67 above) and the reimbursement rate was therefore artificially inflated by $85\% \times (\text{AWP} - \text{AWP}_{\text{but-for}})$. However, because the AWP was to be designated as the lesser of the median AWP for all generics or the lowest brand AWP, calculation of damages would require calculating $\text{AWP}_{\text{but-for}}$ for all generics and branded versions of relevant drug.

The data required for these calculations for these drugs are not available to me; therefore, I cannot undertake the requisite calculations. Hence, damages for all multi-source Part B drugs under Medicare are assumed to be 0.00 for 2004. This is a conservative assumption.

b) For non-Medicare reimbursements for Sub-Class 3

- For damages to this Sub-Class, for single-source drugs I use the liability yardstick $\text{Spread}_{jk}^{\text{but-for}} = 30\%$. I allow the single-source drugs to remain subject to damages and use the same yardstick for six months after the first generic launch.⁶⁸ At that point, I assume multiple generic launches occur, unless I have information to the contrary. Once multiple generics launch, I assume MAC pricing is introduced and that damages are calculated as discussed immediately below for multi-source drugs.
- For multi-source drugs, I assume MAC pricing is in use; I assume that the MAC pricing does not reference AWP; and therefore the drugs are not subject to damages. This is a conservative assumption.⁶⁹

⁶⁸ This treatment is supported by PBM contracts for reimbursement of self-administered single-source orals (see p. ESI-277-00002070 found in ESI-277-00002066-77) and by the practices of DHHS with respect to the Federal Upper Limit (p. 12 of Attachment D of my September 3, 2004 Declaration).

⁶⁹ These assumptions are conservative for a variety of reasons. For example, as I have discussed in my previous Declarations, PBMs do not always go to MAC with multiple generic entry. Likewise, MAC pricing frequently references AWP.

C. Methodology for Damage Calculation

64. For those units (q_{jkt} , see notation below) of those drugs (by NDC) found in excess of the liability threshold (as identified in Attachment I), I trace their distribution through the provider distribution schematic in Figure 2. I calculate damages for Sub-Classes 1 & 2 as follows:

$$(2a) \quad \text{Overcharges}_{jkt} = 20\% * \Delta p_{jkt} * q_{jkt};$$

where Overcharges_{jkt} is the measure of overcharge damages at Node D for drug j (by NDC) of manufacturer k in year t . Δp_{jkt} for $t = 1991$ -2004 is calculated as follows:

a) For Medicare single-source Part B drugs:

- $\Delta p_{jkt} = (\text{AWP}_{jkt} - \text{ASP}_{jkt})$, for $t = 1991$ -1997;
- $\Delta p_{jkt} = (95\% * \text{AWP}_{jkt} - \text{ASP}_{jkt})$, for $t = 1998$ -2003;
- $\Delta p_{jkt} = x\% * (\text{AWP}_{jkt} - 1.30 * \text{ASP}_{jkt})$, for $t = 2004$, where $x\%$ is determined by the specific NDC; it ranges from 80%-95%, with the default value being 85%;⁷⁰ and
- q_{jkt} = the units of single-source drug j manufactured by Track One Defendant k and reimbursed under Medicare Part B.

b) For Medicare multi-source Part B drugs:

- $\Delta p_{jkt} = (\text{AWP}_{jkt} - \text{ASP}_{jkt})$, for $t = 1991$;
- $\Delta p_{jkt} = (\text{Median generic AWP} - \text{ASP}_{jkt})$, for $t = 1992$ -1997;
- $\Delta p_{jkt} = (95\% * \text{Minimum}\{\text{Median generic AWP, lowest branded AWP}\} - \text{ASP}_{jkt})$, for $t = 1998$ -2003;
- $\Delta p_{jkt} = 0.00$, since $\text{AWP}_{\text{but-for}}$ cannot be calculated for 2004 without data on all generic and branded ASPs in the market; and
- q_{jkt} = the units of multi-source drug j manufactured by Track One Defendant k and reimbursed under Medicare Part B.

Distribution (at Node D) to Medicare beneficiaries (consumers) and TPPs occurs once all Medicare Part B copay damages are calculated.

In the damage calculation, I first calculate damages to Sub-Class 1 (a national class) and all commercial payors in the U.S. Having performed that calculation, I

⁷⁰ Recall from footnotes 13 and 67 that the relevant AWP and ASPs are those of April 1, 2003.

disaggregate those overcharge damages incurred by commercial payors for physician-administered drugs reimbursed by TPPs subject to Massachusetts state law (Sub-Class 2).

65. I calculate damages for non-Medicare units using the formulation introduced in ¶ 25 of my September 3, 2004 Declaration, which made use of the notation developed in ¶¶ 21-23 of that Declaration. Specifically, ignoring the subscripts j and k on the spread above, the actual reimbursement rate allowed by the commercial payors can be derived from the inflated AWP as allowed amount = $AA = AWP - x\% = (100\% - x\%) * AWP$, for any $x\%$ ⁷¹ and where the retail dispensing fee (df) has been ignored for obvious reasons. Then the but-for $AA = AA_{\text{but-for}} = AWP_{\text{but-for}} - x\% = (100\% - x\%) * AWP_{\text{but-for}}$. The injury or overcharge per unit reimbursed is $(AA - AA_{\text{but-for}}) = (100\% - x\%) * (AWP - AWP_{\text{but-for}}) = (100\% - x\%) * (\text{Spread} - \text{Spread}^{\text{but-for}}) * ASP$.

Using this formulation, I calculate aggregate non-Medicare overcharge damages as follows:

$$(2b) \quad \text{Aggregate overcharge damages} = (AA - AA^{\text{but-for}}) * \text{total units reimbursed}, \\ = (100\% - 2.5\%) * (\text{Spread} - \text{Spread}^{\text{but-for}}) * ASP * q_t$$

where 2.5% represents the average discount off AWP for physician-administered drugs reimbursed in a non-Medicare context by all commercial payors, as surveyed and reported by MedPAC,⁷² and q_t is the total units of the relevant NDC of the relevant drug reimbursed in period t under the non-Medicare branch of the schematic in Figure 2.

As noted in ¶ 63.b) above, I calculate non-Medicare overcharge damages for all single-source drugs until multiple generics launch, at which point I assume that MAC is put into effect and I set the overcharge damages to \$0.00 beginning in the following year.

As with the Medicare damage, I first calculate aggregate overcharge damages in the U.S. for all non-Medicare units being reimbursed. I then disaggregate that total to overcharge damages borne by all U.S. consumers (through inflated coinsurance payments

⁷¹ As noted in ¶¶ 22.c) and 28.a) above, the MedPAC Report indicates that $x\%$ can range from $\pm 15\%$ over the Class. See also the next footnote.

⁷² See MedPAC Report, Table 9-2. The average weighted (by the number of respondent payors) reimbursement was 97.55%AWP. I round that discount to (100%-2.5%) for ease of calculation and exposition.

and inflated out-of-pocket payments) and overcharge damages borne by all TPPs in the U.S., using the data described with Figure 2 for that disaggregation. I finally disaggregate from that national total the overcharge damages to the Massachusetts members of Sub-Class 3.

66. The damage calculations are reported in Attachment J by manufacturer, by Medicare Sub-Classes and for all non-Medicare reimbursements, both nationally and for reimbursements in Massachusetts.

67. Note the following regarding the damage analysis. I have used manufacturer sales data to calculate overcharge damages, which are incurred by the Class members as a result of inflated reimbursement payments to providers. The question arises: Does the use of manufacturer data provide an accurate calculation of overcharges in payor reimbursements to providers? The answer is yes.

68. Manufacturer data are delineated by NDC. The damage calculations in the preceding paragraphs demonstrate the ease with which the crosswalk between J-Codes and NDCs can be accomplished, confirming the finding of the OIG from 1996 for 1994 Medicare claims (see footnote 52). For single-source drugs, all NDCs, including the NDC of the fundamental billing unit are readily available. Claims for reimbursement are calculated as percentages of the relevant AWP; the but-for AWP is calculated using the relevant ASP. For multi-source drugs, the data requirements are somewhat more onerous; however, it is straightforward to identify all the relevant generic and branded alternative NDCs, their AWP, and the but-for AWP.⁷³

⁷³ More specifically, for Medicare and non-Medicare damages, the crosswalk between J-Codes and NDCs has been demonstrated to be particularly easy for single-source drugs. The NDCs by J-Code are listed; the providers can access those NDCs and AWP; the payors can review those NDCs and AWP. Calculation of damages for these drugs is straightforward and formulaic.

For multi-source drugs under Medicare Part B, I identify when any Class drug went generic (i.e., became multi-source), all relevant available generics possible, their AWP (from RedBook) and the median of their AWP for the period 1991 through 2003. This median AWP is the reimbursement alternative to ASP for any multi-source drug sold by Defendants and reimbursed by the Medicare Sub-Classes during the period 1991-1997. Over 1998-2003, the alternative to ASP is the lesser of 95% of the median generic AWP or 95% of the least expensive brand name AWP (also available through RedBook or First DataBank). Hence, the data requirements are clear and the data are readily available from publicly-available sources.

With the amendments altering reimbursement for multi-source drugs under Medicare (see ¶ 20 above) beginning January 1, 2004, the reimbursement alternatives rely upon the actual AWP as of April 1, 2003 and the but-for AWP which is determined by the ASPs of all generic and branded versions of the relevant

69. Payor claims data are delineated by J-Codes. The use of manufacturer data to measure overcharges at the claims level therefore assumes the following: first, that providers do submit claims for the physician-administered drugs that they have purchased in the provision the relevant medical service; second, that the providers are sufficiently profit-maximizing to bill not less than the amount allowed by NDC; third, that providers use NDCs to submit claims to payors, principally by reporting the relevant AWP and units administered (which will be denominated for the actual NDC or the NDC related to the fundamental billing unit); and fourth, that payors have reimbursed according to the AWP provisions of the Medicare statutes and the payment practices and procedures identified in fact discovery and in survey research (e.g., the OIG report (particularly the 1996 Report; see footnote 52) and the MedPAC Report), which are based upon NDC-specific data and/or data for the fundamental billing unit. The first two assumptions are based upon rational economic behavior. I have corroborated the latter two assumptions using claims data made available by Defendant experts (see my Table 4). Those data demonstrate that claims relevant for damages⁷⁴ are reported as standard percentages of AWP or integer multiples of standard percentages of AWP.⁷⁵

NDC as of April 1, 2003. Such ASP data were not available to me for non-Defendant drugs. I therefore do not calculate damages for multi-source drugs under Medicare in 2004.

For non-Medicare reimbursement of physician-administered drugs, I exclude all units from damages for all drugs that have been or have become multi-source (i.e., the year after generic launch). As discussed above, because I have found that commercial payors are slow to implement this MAC pricing rule, I believe this procedure to be conservative from the point of view of aggregate damage calculations.

⁷⁴ That is, excluding claims for \$0.00 and for amounts unrelated to AWP (i.e., that summarize coinsurance for out-patient hospital physician administered drug administration).

⁷⁵ When a claim is submitted by a provider and reimbursed by a payor in terms of a J-Code, price and quantity administered are included in the claim (see the claims data analyses submitted by Dr. Gaier, Mr. Young and summarized above in ¶¶ 42-47 and Table 4 of this Declaration). The claimed amount and quantity is delineated in AWP and units by NDC or by fundamental billing units (which is usually a specific NDC). Multiple NDC units or fundamental billing units reflect multiple units produced by the manufacturer.

In some cases, the claims request reimbursement for amounts that are integer multiples of some percentage of AWP, as clarified in Table 4, reflecting an error in the quantity reported. However, since the claimed amount is a multiple of the relevant percentage of one of the AWP's, the logical conclusion is that the total dollar amount is correct but the quantity misstated in the claim. The use of manufacturer data avoids that misstatement; the fact that the claimed amount is an integer multiple of a percentage of the AWP indicates that the claimed amount properly takes the quantity into account.

D. Summary of Damage Calculations

70. In Attachment J, I summarize the damages for all five Track One Defendants, for the three Sub-Classes and for the U.S. as a whole for those entities included in Sub-Classes 2 and 3. To briefly summarize, I find the following:

- a) Attachments J.1 through J.5 summarize my calculations of damages for all those drugs of each of the five Track One Defendants who's AWP's were artificially inflated. For each Defendant, the amount of damages for Sub-Class 1 are the largest, given the fact that this Sub-Class is national. The damages to Sub-Classes 2 and 3 are smaller, since these damages involve reimbursement for drugs administered in Massachusetts only. The damage calculations by Sub-Class are presented in nominal dollars (that is, summing the damages for all years) and in constant dollars (that is, allowing for pre-judgment interest) which takes account of the fact that compensation for damages that occurred in the early years of the Damage Period is worth more today than it was in those early years.

These damage summaries also appear in Table 1 of the body of this Declaration.

- b) The damages for AstraZeneca (AZ, in Attachment J.1) involve 2 drugs, Pulmicort and Zoladex. Eight BMS drugs are subject to damages (Attachment J.2). Ten GSK drugs are subject to damages (Attachment J.3). Two J&J drugs are subject to damages (Attachment J.4), and five Schering-Plough (S-P) drugs are subject to damages (Attachment J.5).
- c) The supporting Tables to each of these five summary Tables appear in Attachments J.1.a) to J.1.j) through J.5.a) to J.5.j) respectively. For example, for AZ:
 - Attachment J.1.a) calculates damages by NDC by year for Sub-Class 1;
 - Attachment J.1.b) aggregates those damages to the drug level for Sub-Class 1;
 - Attachment J.1.c) calculates damages by NDC to all TPPs nationally for reimbursement of Medicare supplemental coinsurance;
 - Attachment J.1.d) aggregates those damages to the drug level for all TPPs nationally for reimbursement of Medicare supplemental coinsurance;
 - Attachment J.1.e) disaggregates from the national damages those damages by NDC to all TPPs for reimbursement in Massachusetts of Medicare supplemental coinsurance (that is, Sub-Class 2);
 - Attachment J.1.f) aggregates those damages by NDC to the drug level for Sub-Class 2;
 - Attachment J.1.g) calculates damages by NDC to all TPPs and consumers nationally for reimbursement of non-Medicare claims;

- Attachment J.1.h) aggregates those damages to the drug level for all TPPs and consumers nationally for reimbursement of non-Medicare claims;
 - Attachment J.1.i) disaggregates from the national damages those damages by NDC to all TPPs and consumers for reimbursement of non-Medicare claims in Massachusetts (that is, Sub-Class 3);
 - Attachment J.1.j) aggregates those damages by NDC to the drug level for Sub-Class 3.
- d) Attachment J.2.a) to J.2.j) through J.5.a) to J.5.j) present analogous information for the other four Defendants.
- e) The formats of the supporting tables to each Summary Table may differ somewhat given the fact that the data received from each Defendant differed in format and content to some degree. The extent to which such differences occur is clarified in the notes to the Tables, which are present as Attachment J.6.
- f) The data used for identifying total Class units and disaggregating them into the relevant Sub-Classes are described in Attachment J.7.

71. Attachment J has been provided to present the Court with the full context of the calculations supporting the Summary of Damages presented in Table 1 in the body of this Declaration. For purposes of discussing the damage calculations, Table 1 is sufficient. Notice the following in Table 1.

- a) Aggregate damages in 2005 dollars (that is, taking account of the time value of the damages) to Sub-Class 1 range from \$10.1 million for GSK to \$50.2 million for S-P.
- b) Aggregate damages to Sub-Class 2 range from \$1.6 million for GSK to \$7.9 million for S-P. If all states and the District of Columbia were to be included in this Sub-Class, the damages would range from \$60.6 million for GSK to \$297.9 million for S-P.
- c) Aggregate damages to Sub-Class 3 range from \$1.2 million for S-P to \$12.3 million for GSK. If all states and the District of Columbia were to be included in this Sub-Class, the damages would range from \$47.0 million for S-P to \$464.8 million for GSK.

X. Summary and Conclusions

72. The formulaic methodology implemented in this Declaration is based upon sound economic theory and quantitative methods, a valid yardstick approach and a sufficiently complete incorporation of the realities of the business and regulatory practices

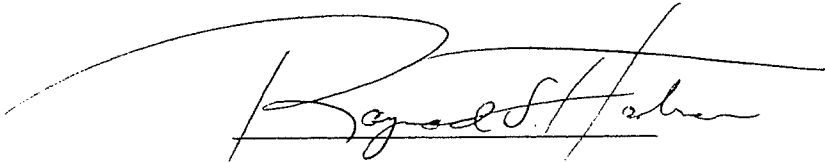
determining the markets for the administration of and reimbursement for physician-administered drugs.

I have implemented my formulaic methodology for the demonstration of causation and liability and, having determined liability on an NDC basis annually, I have calculated of aggregate Class-wide damages for the three Sub-Classes for those drugs for which liability was demonstrated. I have found that all five Defendants were liable for artificially inflating the AWP's of some of their drugs for some portion of the Damage Period. I have found that the amount of damages is substantial, overall and for each Defendant.

I have also found that the structure and approach of the formulaic methodology is the same for all drugs and all five Defendants.

I declare under penalty and perjury that this Declaration is true and correct.

Executed on December 15, 2005



Raymond S. Hartman

Attachment A

July 2005

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DEGREES

B.A. (MAGNA CUM LAUDE) Princeton University 1969
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Ph.D. DISSERTATION

An Oligopolistic Pricing Model of the U.S. Copper Industry (MIT, 1977)

HONORS, SCHOLARSHIPS, AND FELLOWSHIPS

1969-71	National Science Foundation Fellowship to MIT
1965-69	Alfred P. Sloan Scholarship to Princeton
1969	Woodrow Wilson Fellowship Honorable Mention
1965	National Merit Scholarship Finalist

RESEARCH AND TEACHING INTERESTS

Econometrics/Statistics
The Economics of Regulated Industries
Energy and Environmental Economics
Microeconomics
Industrial Organization
Law and Economics

POSITIONS

1967-1969	Research Staff, Financial Research Center and Center for Economic Research, Princeton University
1970	Research Staff, Board of Governors, Federal Reserve Board, Washington, DC
1972-1992	Consultant and Staff Economist, Arthur D. Little, Inc.
1977-1984	Research Faculty, Massachusetts Institute of Technology
1977-1983	Assistant Professor, Department of Economics, Boston University
1983-1989	Associate Professor, Department of Economics, Boston University
1983-1988	Principal & Academic Principal, The Analysis Group
1988-1993	Visiting Associate Professor/Visiting Faculty, Boalt School of Law, University of California, Berkeley
1988-1995	Founding Principal, The Law and Economics Consulting Group
1995-1996	Vice President, Charles River Associates
1996-1999	Senior Consultant, Charles River Associates
1996-2000	Director, Cambridge Economics, Inc.
2000-2004	Special Consultant, Lexecon Inc.
1997-	Director and President, Greylock McKinnon Associates

OTHER PROFESSIONAL ACTIVITIES

Research Referee, *Bell/Rand Journal of Economics, Resources Policy, IPC Science and Technology Press, Management Science, Land Economics, Science, Energy Journal, Applied Economics, Econometrica, Review of Economics and Statistics, Journal of Business and Economic Statistics, International Economic Review, Journal of Economics and Management Strategy, Pakistan Journal of Applied Economics, Journal of Health Economics, American Economic Review*

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ADL, Southern California Edison Projections of Conservation Goals 1982-1986, Report to the California Public Utilities Commission for Southern California Edison, October 1981.

ADL, Estimate of Conservation Penetration for the Southern California Gas Company Service Area, 1981-1986, Report to the Southern California Gas Company, November 1981.

ADL, Electricity and Natural Gas Conservation Potential in the San Diego Gas and Electric Service Territory, Report to the Public Utility Commission of the State of California, April 1982.

ADL, Integrated Conservation Planning/Load Forecasting System Technical Users Guide, Report to San Diego Gas and Electric Company, Vols. I and II, Summer 1982.

ADL, A Method for Evaluating Residential Conservation Programs: Interim Report, Report to the Electric Power Research Institute, RP 1587, March 1983.

ADL, Measuring the Impact of Residential Conservation, Volume II: An Econometric Analysis of Portland General Electric Company Data, Report to the Electric Power Research Institute, EPRI EA-3606, September 1985.

ADL, Measuring the Impact of Residential Conservation, Volume III: An Econometric Analysis of General Public Utilities Inc. Data, Report to the Electric Power Research Institute, EPRI EA-3606, Project 1587, May 1986.

ADL, Measuring the Impact of Residential Conservation, Volumes IV: A Comparison of Alternative Methods, Report to the Electric Power Research Institute, EPRI EA-3606, Project 1587, May 1986.

ADL, Evaluation of EUA's Proposed Acquisitions of Unitil and Fitchburg Electric, Report to Gaston and Snow, March 12, 1990.

Hartman, "Critical Review of Selected Energy End-Use Models and Proposed Specifications for PG&E End-Use Modeling Efforts," Arthur D. Little, Inc., Working Memorandum #13 for Pacific Gas and Electric Co., June 1979, Arthur D. Little, San Francisco.

Hartman, "Potential State-of-the Art Energy Demand Models for Use in Developing an Integrated Natural Gas Forecasting and Conservation Planning System for Southern California Gas Company," Arthur D. Little Working Paper, June 1981, Arthur D. Little, San Francisco.

Hartman, "A Critical Review of the Delmarva 1981-2000 Load Forecast," with James C. O'Keefe, Arthur D. Little Working Paper, September 1981, Arthur D. Little, San Francisco.

Hartman, "Analyzing and Measuring the Effects of Utility Sponsored Conservation Programs," Arthur D. Little

Energy Group Discussion Paper, September 1982, Arthur D. Little, San Francisco.

UNPUBLISHED WORKING PAPERS

"An Examination of the Use of Probability Modeling for the Analysis of Inter-fuel Substitution in Residential Fuel Demand," with M. Hollyer, MIT Energy Lab Working Paper #MIT-EL-77-018WP, July 1977.

"A Critical Survey of Three Copper Industry Models and Their Policy Uses," MIT Energy Lab Working Paper #MIT-EL-77-028WP, September 1977.

"The Evolutionary Model of Technical Change: Historical Evidence from Great Britain and the United States:, with D. Wheeler, mimeo, December 1977.

"A Critical Review of Single Fuel and Interfuel Substitution Residential Energy Demand Models," MIT Energy Laboratory Report #MIT-EL-78-003, March 1978.

"A Generalized Logit Formulation of Individual Choice," MIT Energy Laboratory Working Paper #MIT-EL-79-010WP, February 1979.

"A Model of Residential Energy Demand," MIT Energy Laboratory Working Paper, #MIT-EL-79-041WP, August 1979.

"The Incorporation of Solar Photovoltaics into a Model of Residential Energy Demand," MIT Energy Laboratory Working Paper #MIT-EL 80-014WP, May 1980.

"Consumer Choice Among Alternative Fuels and Appliance Technologies: An Analysis of the Effects of Alternative Energy Conservation Strategies," MIT Energy Laboratory Working Paper #MIT-EL 82-036WP, June 1982.

"Estimation of Hedonic Supply Curves For Residential Water Heaters Using Technical Data and Federal Testing Guidelines," with Alan Cox and Mary Litterman, MIT Energy Laboratory Working Paper #MIT-EL 82-037WP, June 1982.

"A Monte Carlo Examination of the Heckman and the Manski-Lerman Estimators in Discrete/Continuous Models of Demand," October 1986.

"The Value of Service Reliability: Alternative Welfare Measures," with C.K. Woo, October, 1988.

"The Use of Hedonic Analysis in Defining and Measuring Market Size: The Extension of the Merger Guidelines to Heterogeneous Products," Working Paper No. 91-12, Program in Law and Economics. School of Law, Boalt Hall

SELECTED CONSULTING ASSIGNMENTS AND EXPERT TESTIMONY/DEPOSITION

1972-1975: In consultation with Arthur D. Little, Inc., Dr. Hartman developed economic impact models to assess the effects of environmental regulations upon the U.S. pollution abatement equipment industry and upon a particular U.S. copper smelting company.

1972-1975: In consultation with Arthur D. Little, Inc., Dr. Hartman developed economic models to assess the regional macroeconomic and industrial impacts of alternative strategies to promote tourism-related industries. The models were used in the United States by the states of Maryland and Maine and for the Philadelphia Bicentennial

Commission. Internationally, the models were used by the Ministry of Planning of Mexico to assess the national and regional importance of tourism coming into Acapulco.

1976-1977: Consultation with Arthur D. Little, Inc. for the U.S. Environmental Protection Agency. The effort involved the design, estimation and implementation of an econometric simulation model that was used to assess the impact of pollution abatement legislation on the U.S. copper industry. The model was designed to incorporate engineering cost estimates attributable to the abatement legislation while accounting for the noncompetitive pricing behavior in the industry. The model was used to evaluate and revise proposed abatement legislation. This analysis was the basis for Dr. Hartman's Ph.D. dissertation and several of his publications.

1977-1982: As an expert for Kohn, Milstein, Cohen and Hausfeld, Dr. Hartman analyzed the presence of a price-fixing conspiracy among the major U.S. copper producers during the 1970's. His testimony addressed issues of liability and developed a model of damages. See

Affidavit to United States District Court for the Southern District of New York, J.N. Futia Co., Inc., Plaintiff, Against Phelps Dodge Corporation, et al., Defendants, 78 Civ. 4547 (ADS), 1978.

Deposition for United States District Court, Southern District of New York for Reading Industries, Inc., et al. (Plaintiffs) against Kennecott Copper Corporation, et al. (Defendants), 17 Civ. 1736 (MEL), 1982.

1977-Present: One of Dr. Hartman's main areas of expertise and experience involves regulated industries and electric and gas utilities. His consulting assignments have included load forecasting, evaluation of conservation and load management programs, econometric cost analysis, analysis of revenue requirements and rate-making, analysis of value of service reliability, the analysis of mergers and acquisitions, analysis of industry restructuring and analysis of contract damages arising from DOE's partial breach of the Standard Contract regarding storage of nuclear waste. In these assignments, Dr. Hartman has consulted for such clients as Arizona Public Service, the Pacific Gas and Electric Company, the Southern California Edison Company, the Southern California Gas Company, the San Diego Gas and Electric Company, Portland General Electric Company, Bonneville Power Administration, General Public Utilities, Northeast Utilities, Niagara Mohawk Power Corporation, the Delmarva Power Corporation, Florida Power Corporation, Sithe Energies, the California Energy Commission and Public Utilities Commission, the Missouri Public Service Commission, the Rhode Island Division of Public Utilities, the Attorney General of the State of Massachusetts, the Electric Power Research Institute, the Gas Research Institute, the U.S. Department of Energy, the U.S. Department of Justice, the World Bank, and the governments of Indonesia and Thailand. This experience is reflected in the majority of his publications and reports.

1979: Working for the California Energy Commission, Dr. Hartman developed and presented a Statement of Opinion and Critical Review of Selected Energy End-Use Models and Proposed Specifications for PG&E End-Use Modeling Efforts before the California Energy Commission Hearings on Utility Construction and Siting, November 26-30, 1979.

1984: Testifying expert for the class of all individuals who employed the services of members of Massachusetts Furniture and Piano Movers Association. The analysis developed an econometric model to assist in certifying the class and measuring the damages common to that class. See

Affidavit to United States District Court for the District of Massachusetts in the Matter of Kenett Corporation et al v. Massachusetts Furniture and Piano Movers Association Inc. et al, May 1984, Civil Action No. 82-140-Z.

1984-1986: In consultation with the U. S. Postal Service, Dr. Hartman identified appropriate econometric methods for analysis of the determinants of Postal Service costs. The particular methods he suggested were "hedonic" cost techniques, which are specifically designed to account for the fact that both increased levels of production and improved product attributes increase costs. The techniques assisted the Postal Service in quantification of the cost impacts of the attributes of service quality for alternative classes of service. For example, the techniques allowed for

estimation of the differential cost impacts of alternative service priorities, size and weight attributes of the various classes of mail.

He later applied these techniques for a group of second class mailers. The analysis was introduced before the Postal Service Commission to assess whether proposed postal rate changes reflected actual costs.

1984-1986: The development of econometrically-based strategic planning models, which allow for estimation of the effects on corporate profits of alternative product design and pricing strategies. The models allow for examining specific design strategies by explicitly incorporating detailed product attributes. The models were developed for Westin Hotels and Shell Oil. The Westin models have been implemented into an interactive PC tool that facilitates pricing decisions at the front desk.

1985: For analysis presented before the International Trade Commission, Dr. Hartman helped develop and estimate a model to evaluate the domestic effects of importation of certain synthetic aramid fibers. The analysis was used in adjudicating an international patent infringement complaint.

1985-1986: Dr. Hartman participated in an analysis of one of the nation's largest mutual funds. The study was undertaken as part of a class action alleging inappropriate management fees. The study assessed competition in the money market mutual fund industry. It measured investors' sensitivity to changes in yield and to the level of services provided. It also statistically identified the determinants of the costs of providing mutual fund services.

1985-1986: The development for GTE Laboratories of econometric demand models for analysis and measurement of the determinants of demand for telecommunications services. The models explicitly address the separate customer decisions to subscribe to one of several telecommunications carriers and the demand for telecommunications services, conditional upon the subscription decision. The analysis was employed by GTE to assist their subsidiary, GTE Sprint, in the design of marketable services, where the services were differentiated by tariff, perceived service quality, provider reputation, and specialized customer services. The analysis is summarized in the paper

"Estimation of Household Preferences for Long Distance Telecommunications Carrier", Journal of Regulatory Economics, Volume 6, 1994.

1985-Present: Dr. Hartman has performed a variety of economic damage analyses in cases of personal injury, wrongful injury and wrongful death. He has worked for both plaintiff and defendant. He has been deposed in such matters as recently as 1995.

1986: For a major natural gas pipeline, preparation of an analysis of the effects of natural gas deregulation as proposed in the Federal Energy Regulatory Commission's Notice of Proposed Rulemaking No. 436.

1986-1987: Working for the class of owners of selected General Motors' X Cars and VW Rabbits, Dr. Hartman specified and estimated econometric models that assisted in the certification of class and estimation of class damages. The damages flowed directly from allegedly-concealed design flaws in these automobiles. The methods are described in

"The Use of Hedonic Analysis for Certification and Damage Calculations in Class Action Complaints," with M. Doane, The Journal of Law, Economics and Organization, Fall, 1987.

1986-1987: Development of damage models for litigation in high technology industries. The models were developed in several cases. One involved alleged patent infringement by a major Japanese semiconductor firm, and the second involved market foreclosure of a domestic minicomputer emulator. In these efforts, Dr. Hartman developed econometric models to estimate the market potential, absent the violation, for the particular product foreclosed or whose patent was infringed. The methods are described generically in

"Product Emulation Strategies in the Presence of Reputation Effects and Network Externalities: Some Evidence from the Minicomputer Industry," with D. Teece, Economics of Innovation and New Technology, Volume 1, 1990.

1987: Analysis of the competitive effects of relaxing the restrictions on the Bell Regional Operating Companies regarding their vertical extension upstream into equipment manufacture and downstream into the provision of selected telecommunication services. The study was introduced before Judge Greene in the triennial review of the divestiture of the Bell operating companies from AT&T.

1987-1988: For a major gas utility, participation in analysis of the economic effects arising if bypass of an existing pipeline were allowed by state and federal regulation. The analysis developed methods for assessing when competitive bypass is socially desirable. The analysis also developed and used an econometric model to simulate the effects of bypass on demand and prices.

1988: Analysis of the competitive effects the acquisition of trade secrets through the predatory hiring of a competitor's essential labor force. See

Analysis submitted in testimony in the case Universal Analytics Inc. v. MacNeil Schwendler, Corp.

1988-1989: As part of their proposed acquisition of Public Service of New Hampshire, Dr. Hartman was retained by Northeast Utilities, Inc. to develop and estimate load forecasting models. The models were used to assess the demand implications of alternative rate assumptions proposed as part of the acquisition. The forecasts were introduced as part of Northeast Utilities' filings before the bankruptcy court, the state public utility commissions, the SEC and the FERC.

1989: As part of major antitrust litigation against the leading vendors of airline computer reservation systems, Dr. Hartman helped develop liability analysis and models for the estimation of damages.

1989: As a proposed testifying expert for Parnelli Jones, Inc., Dr. Hartman analyzed the antitrust implications of Firestone's retail trade practices, particularly alleged vertical and horizontal restraints of trade. He designed damage models for the alleged violations.

1989 - Present: Dr. Hartman has performed and continues to perform the market analyses required for Hart-Scott-Rodino applications and second requests supporting mergers and acquisitions in a variety of industries, including specialty chemicals, airlines, health care and medical diagnostic products, and energy products and services.

1989-1990: Dr. Hartman participated as a principal investigator and testifying expert for the Division of RatePayer Advocates of the California Public Utility Commission in an analysis of the economic and legal implications of the proposed merger between Southern California Edison Company and San Diego Gas and Electric Company. Dr. Hartman's responsibilities included overall study design, econometric analysis of scale and scope economies arising with the merger, and analysis of efficiencies purportedly arising with the coordination of the demand-side management programs of the two utilities. His direct and surrebuttal testimony is found in

California Public Utilities Commission, Division of Rate Payer Advocates, Report on the Proposed Merger of the Southern California Edison Company and the San Diego Gas and Electric Company, Volume V, Chapter II, Application 88-12-035, February, 1990, Exhibit 10,500; and

California Public Utilities Commission, Division of Rate Payer Advocates, Report on the Proposed Merger of the Southern California Edison Company and the San Diego Gas and Electric Company, Surrebuttal: Econometric Analysis of Merger Impacts, Application 88-12-035, July, 1990, Exhibit 10,511.

1989-1990: Working with Arthur D. Little, Inc., Dr. Hartman participated as a principal investigator and testifying expert in a merger study for several small New England utilities within Nepool. Dr. Hartman designed and

implemented a statistical study of returns to scale and scope in the industry. Using the statistical results, Dr. Hartman developed opinions regarding the efficiency effects of the proposed merger. His analysis appears as an independent Appendix to

Arthur D. Little, Inc., Evaluation of EUA's Proposed Acquisitions of UNITIL and Fitchburg, Report to Gaston and Snow, March 12, 1990, presented in support of the acquisition to the Securities and Exchange Commission and the New Hampshire Public Utilities Commission.

1990: Working for a group of commodity futures exchanges, Dr. Hartman participated as Principal Investigator in a critical review of a statistical and econometric study performed by the Commodity Futures Trading Commission. The CFTC study was developed to assess the effects of dual trading on commodity futures markets, in order to implement proposed regulations curtailing such trading.

1990: Working with Barakat and Chamberlin, Inc., Dr. Hartman developed a Ramsey pricing model for Arizona Public Service Corporation. The Ramsey pricing model was used to develop and explore alternative rate strategies for a variety of residential, commercial and industrial market segments. The analysis was submitted in formal rate hearings.

1990-1992: Working with the Technology Research Center of Arthur D. Little, Inc. for the United States Postal Service, Dr. Hartman specified and estimated econometric models to analyze the determinants of productivity for the largest 120 post offices in the United States. The econometric models are being used to identify the most and least productive offices, with the purpose of learning from the performance of the most productive offices in order to improve the performance of the least productive offices. The models are being used to design and implement incentive regulation mechanisms to increase productivity across post offices.

A second set of econometric models have been specified and estimated to quantify the effects of the attributes of alternative postal services and rate classes upon total postal service costs. The results of this analysis are being used to design postal rates for alternative classes of service which reflect the real costs of providing the services. The analysis and its results will be introduced into the postal rate hearings.

1990-1997: Working with the World Bank, Dr. Hartman has specified and is estimating a set of econometric models to measure both the level and types of pollutants emitted by United States plants and establishments and the costs of abating those pollutants. The models identify and quantify, at the plant level, the relationship between the emission of approximately 300 pollutants and the scale of production, the types of technology used, the age and characteristics of the plant and equipment used, the extent to which abatement equipment has been installed, and the costs (capital and operating) of abating alternative pollutants.

The models will be used in the following ways in developing countries and Eastern European countries: to assist the countries to predict and assess the environmental implications of reliance upon certain technologies and industries in development; to assess the effectiveness of alternative regulatory methods for abating pollution, including effluent standards, effluent taxes, effluent licenses, technology standards, effluent banks, and alternative property right schemes; to implement incentive regulation mechanisms to better stimulate abatement compliance; and to identify and prioritize those industries that can abate certain pollutants at least cost.

As part of this effort, Dr. Hartman has also designed a specific incentive regulation system for pollution abatement compliance in Indonesia. The system is based upon the most recent theory in regulated incentive mechanisms. The system will ultimately evolve into an effluent bank or a system of effluent fees. If the effort is successful, it will form the basis for environmental institutions in other developing countries. In the process of designing this system, he has reviewed the institutional and statutory basis for environmental policy in Indonesia.

Also as part of this work, Dr. Hartman is in the process of designing the institutional and statutory structures for Environmental Protection Agencies in a variety of developing countries. The institutional structures will be designed to articulate and implement pollution abatement policies that are informed by the econometric modeling described above.

1991: Dr. Hartman participated as a principal investigator and testifying expert for the Missouri Public Service Commission in a critical analysis of the proposed merger between Kansas Power and Light Company and Kansas Gas and Electric Company. Dr. Hartman's responsibilities included overall study design, analysis of scale and scope economies arising with the merger, analysis of unanticipated transitional cost arising with the merger and an econometric event study of the stock market's response to the merger. His testimony appears in

A Critical Analysis of the Proposed Merger Between Kansas Power and Light Company and Kansas and Electric Company, Report to the Missouri Public Service Commission, March 25, 1991.

1991: Working for the Resolution Trust Corporation in its litigation against Michael Milken and Drexel Burnham Lambert Inc., Dr. Hartman developed data and econometric models to measure the size of the relevant antitrust markets dominated by Drexel and to estimate the size of the economic damages produced by Drexel's alleged monopolization of those markets.

1991-1992: Working for the Indonesian government and the United States Agency for International Development, Dr. Hartman critically reviewed the structure of the Indonesian electric power industry and the institutions regulating that industry. The purpose of the analysis was to assist the government with privatizing their energy industries. His analysis focused upon the following: developing better data and models for predicting demand and supply; identifying and implementing more efficient industrial structures; and developing better regulatory regimes.

1992: Working for the World Bank, Dr. Hartman designed methods to measure and compare the social value of the environmental effects of alternative development projects, at the microeconomic and macroeconomic levels. His analysis focused upon standard and contingent valuation survey approaches and their use in econometric settings.

1992-1993: Working for the World Bank in Bangkok, Dr. Hartman characterized and critically analyzed the environmental effects of Thailand's energy use patterns. He focused upon the use and production of electric power, petroleum, coal and natural gas. He developed recommendations for environmental policy changes that included, but were not limited to, fuel taxes, effluent standards, technology standards, and privatization of environmental monitoring within a "bubble" policy approach.

1992-1993: Working for a biomedical company (a producer of vascular grafts) in an antitrust situation, Dr. Hartman designed and implemented survey techniques and econometric models to measure the size of the relevant markets and market power within those markets.

1992-1993: In a proceeding before the International Trade Commission, Dr. Hartman critiqued ITC econometric methods used for estimating elasticities of demand, supply and substitution among domestic and imported products. His focus was selected steel products. He formulated and estimated alternative models and methods to improve the existing estimates. He developed presentation materials for the Commission and testified before the Commission. His testimony is included in

LECG, Petitioners' Economic Testimony in the Matter of Certain Carbon Steel Flat Products, Final Hearing before the United States International Trade Commission, June 29-30, 1993; and

LECG, Petitioners' Post Hearing Brief in the Matter of Certain Carbon Steel Flat Products, before the United States International Trade Commission, July 7, 1993.

1992-1997: Working for the World Bank, Dr. Hartman has designed and is currently implementing a set of regional econometric/engineering models that accurately portray and predict the economic, environmental, infrastructural and socio-demographic effects of large-scale, World-Bank-funded infrastructural projects. The models combine input-output and econometric methods.

Given the Bank experience that many of their financially-sponsored projects create significant unanticipated

environmental effects, the models are designed to be broad and comprehensive enough to incorporate and predict all important effects. The models systematically characterize the relationship between resource-based economic growth and the regional environment in which that growth occurs.

The models are currently being implemented for assessing project developments in the Carajas region of the Brazilian Amazonian rain forest, which is a large, dynamic and ecologically sensitive frontier area. The methods implemented for Brazil will be generalized for analysis of economic growth in ecologically similar areas, such as the Lake Baikal region of the former Soviet Union.

1993-1994: Working for the Commonwealth of the Northern Mariana Islands, Dr. Hartman developed and presented testimony rebutting a complaint by the United States Department of Justice that the Public School System of the Commonwealth practiced employment discrimination against teachers of Filipino and native Carolinian origin. Dr. Hartman's testimony examined both hiring and compensation practices. His testimony included hedonic regression analysis of the market for public school teachers in the islands. This analysis measured how teacher attributes and qualifications determined teacher salaries and hiring. The results of the analysis indicated that salary differentials resulted from differences in teacher qualifications rather than discrimination.

1993-Present: Working either as the testifying expert or supporting other testifying experts, Dr. Hartman has participated in a variety of patent infringement cases. He has developed, supported and estimated alternative theories and measures of damages for manufacturers of coaxial cable and a variety of alternative medical devices.

1993-1998: Working as the testifying expert, Dr. Hartman developed models estimating the damages to the business of a construction general contractor that were caused by the malicious prosecution of the contractor's insurance company.

1994: Working for the United States Wheat Associates in a proceeding before the ITC, Dr. Hartman designed and implemented an econometric study to assess and quantify the extent to which Canadian Wheat Board imports into the U.S. undersold domestic supplies and thereby materially interfered with the United States Department of Agriculture Wheat Program. The econometric study was hedonic. The study measured how non-price attributes are valued in U.S. wheat markets. The non-price attributes analyzed included such things as protein content, shipment defects, moisture content and a number of end-use performance characteristics. Having measured the value of these attributes in U.S. markets, the analysis indicated how the Canadian Wheat Board fixed import prices below market levels, given the attributes of the imported wheat.

1994: Working as a testifying expert for Gallo Wines in a proceeding before the ITC, Dr. Hartman designed and implemented a statistical study of the US wine industry that analyzed the impacts of Chilean wine imports upon the domestic industry that would result from the inclusion of Chile in a Free Trade Agreement with the US.

1994: Working as a testifying expert for an insurer of a member of the Asbestos Claims Facility and Center for Claims Resolution, Dr. Hartman developed a statistical analysis estimating alternative indemnification liabilities expected under the Settlement Share Analysis of the Center for Claims Resolution and under the tort system. The results were used to make strategic decisions regarding the desirability of participating in the Class Action Settlement relative to litigating the claims.

1994: Working for several regional Bell Operating companies, Dr. Hartman has developed models and survey procedures to analyze and quantify the determinants of demand for local services, long-distance services and PCS services. The models quantify how consumers respond to and select among alternative carriers who differentiate their services by performance attributes and vendor reputation. The models also estimate the level of service demand, conditional upon the selection of service vendor. The models are being used to quantify the nature of competition among local carriers and long-distance carriers in the Intralata market. The models are also being used to help develop bidding strategies for specific RBOCs as they participate in the FCC auctions for the PCS spectra.

1995: Working as a testifying expert for a group of independent television stations and program producers,

Dr. Hartman developed an econometric analysis of the impacts of the Prime Time Access Rule (PTAR) upon the economic performance of independent television stations. The analysis was submitted to the Federal Communications Commissions as part of their consideration of the repeal of the Rule. Dr. Hartman's analysis proved that PTAR had a strong, statistically significant effect upon the economic performance of these stations, and that its repeal would adversely impact them.

His testimony is included in

The Economic Effects of Repealing the Prime Time Access Rule: Impact on Broadcasting Markets and the Syndicated Program Market, Report prepared by LECG and presented before the Federal Communications Commission, MM Docket No. 94-123, March 7, 1995.

1995: Working for a big six accounting firm, Dr. Hartman designed and implemented a hedonic regression analysis to calculate transfer prices under the comparable uncontrolled price (CUP) method. The analysis is discussed in

"The Use of Regression Techniques in Transfer Price Analysis," with Delores Wright and J.D. Opdyke, European Taxation, 1996.

1995-1996: Working as the testifying expert for a major high tech firm in New England, Dr. Hartman has developed rebuttal and affirmative testimony to rebut claims of age discrimination in the termination of a group of employees over forty. His rebuttal testimony involved critically reviewing statistical analyses purporting to demonstrate disparate treatment and disparate impact. His affirmative testimony has involved designing and implementing econometric models to identify and estimate those factors actually determining the compensation and termination decisions of the defendant.

1995-1996: Working as the testifying expert for the Office of Attorney General of the State of Massachusetts, Dr. Hartman has analyzed and helped develop the State's positions on the following issues: restructuring the electric utility industry in Massachusetts and New England; regulating those entities in the restructured industry that will remain subject to regulation; and valuing those assets that may be stranded as a result of restructuring. As part of the effort, Dr. Hartman also critically reviewed the restructuring proposals of the largest utilities in the state. His testimony appears in

"The Market for Power in New England: The Competitive Implications of Restructuring," a report prepared for the Office of the Attorney General, Commonwealth of Massachusetts and submitted February 16, 1996 in support of their filing to the Department of Public Utilities as part of DPU 95-30, which was initiated August 15, 1995.

1995-1996: Working as the testifying expert, Dr. Hartman represented Florida Power Corporation in a contract dispute with Independent Power Producers. His analysis and testimony focused upon issues of damages incurred as a result of a breach of contract.

1995-1999: Working with a team of economists, Dr. Hartman represented the group of wholesalers in the retail prescription drug price fixing conspiracy case. His efforts included industry analysis and participation in cross examination of plaintiffs' experts.

1996: Working as the testifying expert for the Division of Public Utilities of the State of Rhode Island, Dr. Hartman has analyzed and helped develop the State's positions on restructuring the electric utility industry in Rhode Island and New England, for both the State's Public Utilities Commission and the FERC. As part of the effort, Dr. Hartman also critically reviewed the restructuring proposals of some of the utilities in the state. His testimony appears in

"The Division Plan to Restructure the Electric Utility Industry in Rhode Island," Volume 2 of Supporting Testimony to the State of Rhode Island and Providence Plantations Public Utilities Commission, in re: Electric Industry Restructuring, Docket 2320, April 12, 1996.

1996: Working with a team of engineering firms, an international investment banking firm, a big six accounting firm and several national law firms, Dr. Hartman developed models of demand, supply and futures markets in restructured electric power markets to assist a major industry participant in evaluating specific alternative acquisition strategies.

1996: Working with a team of economists developing evidence for presentation before the High Court of New Zealand, Dr. Hartman critically reviewed and rebutted a variety of econometric analyses of natural gas markets and more broadly-defined energy markets in New Zealand. These analyses were used to determine the size of antitrust markets for a variety of energy products.

1996: Dr. Hartman was retained by a major mid-west utility to critically review and rebut analyses and evidence presented before the FERC and the relevant State Commissions concerning the competitive impacts of the proposed Primergy merger.

1996-2003: Working as the testifying expert, Dr. Hartman analyzed the employment practices and procedures of the Florida Power Corporation during a reduction in force, to assess the validity of a complaint that those practices and procedures resulted in a pattern of age discrimination. In his testimony, Dr. Hartman implemented a variety of statistical and econometric analyses to address and quantify claims of disparate impact and disparate treatment.

1996-1997: Working for US Airways with a team of economists, Dr. Hartman specified and estimated a variety of econometric consumer choice models to measure customer preferences for the services of alternative air carriers in a cross section of US-European origin-destination markets. The models were used to evaluate the economic impacts of both the proposed alliance between American Airlines and British Airways and alternative proposals to condition that alliance.

1996-1997: Working as the testifying expert, Dr. Hartman represented a major national retail pharmaceuticals wholesaler in litigation brought by a regional distributor alleging monopolization of wholesale services to distinct classes of trade. His analysis addressed market definition, the analysis of competition generally and analysis of the competitive impact of specific contractual arrangements.

1997: Working with a team of experts, Dr. Hartman analyzed economic impacts of the construction of the Warrior Run Cogeneration plant which was under construction in Western Maryland and was contracted to sell power to Allegheny Power System's (APS) Maryland subsidiary, Potomac Edison.

1997: Working as the testifying expert for the Office of Ratepayer Advocates of the California Public Utilities Commission, Dr. Hartman critically reviewed the efficiencies estimated by Applicants to be induced by the proposed merger of Pacific Enterprises and Enova Corporation.

1997: Working with a team of economists, Dr. Hartman prepared affirmative and rebuttal testimony in a breach of contract matter in the pharmaceutical industry arbitrated before the International Chamber of Commerce.

1997-2000: Working as the testifying expert, Dr. Hartman developed analysis supporting certification of class and estimation of damages for the class of purchasers of thermal fax paper in the US over the period 1990-1992 who were damaged as a result of a price fixing conspiracy by major suppliers.

1998: Working as the testifying expert, Dr. Hartman analyzed the employment practices, procedures and personnel data of the Florida Power Corporation, in general and in particular, to assess the validity of a complaint that a specific employee had been subjected to racial discrimination.

1998-1999: Working with a team of economists for the Office of the Attorney General of the State of Massachusetts, Dr. Hartman developed and implemented econometric models to analyze and measure the health care costs arising under the Medicaid program that have been attributable to smoking. The analysis appears in the following documents:

David M. Cutler, Arnold M. Epstein, Richard G. Frank, Raymond S. Hartman, Charles King and Joseph P. Newhouse, *The Impact of Smoking on Medicaid Spending in Massachusetts: 1970-1998 -- Report on Methods*, June 15, 1998;

David M. Cutler, et. al., *The Impact of Smoking on Medicaid Spending in Massachusetts: 1970-1998 -- Results From The Inclusive Approach for Adults*, July 1, 1998;

David M. Cutler, et. al., *The Impact of Smoking on Medicaid Spending in Massachusetts: 1991-1998 -- Results From The Disease-Specific Approach for Adults and Overall Summary*, July 11, 1998.

Drawing upon these efforts, Dr. Hartman worked with the same team of experts to analyze the economic impacts of the Master Settlement Agreement and to present their findings to the Tobacco Fee Arbitration Panel.

1999: Working as one of two testifying experts for the Office of the Attorney General of the Commonwealth of Massachusetts, Dr. Hartman critically analyzed potential rate increases relevant to Joint Petitions introduced by both Eastern Enterprises/Colonial Gas Company and Boston Edison/Commonwealth Energy Systems. His testimony appears as

Joint Testimony of Seabron Adamson and Raymond Hartman on Behalf of the Massachusetts Attorney General, in the matter of the Joint Petition of Eastern Enterprises and Colonial Gas Company For Approvals of Merger Pursuant to G.L. c. 164, §§ 96 and 94, DTE 98-128, March 26, 1999.

Joint Testimony of Seabron Adamson and Raymond Hartman on Behalf of the Massachusetts Attorney General, in the matter of the Joint Petition of Boston Edison Company, Cambridge Electric Light Company, Commonwealth Electric Company and Commonwealth Gas Company For Approval of Rate Plan Pursuant to G.L. c. 164, §§ 76 and 94, DTE 99-19, April 30, 1999.

1999-2000: Dr. Hartman was retained by a group of industrial purchasers of copper to develop and implement methods and models to assess liability and measure damages in the matter involving the manipulation of the spot and future prices of copper on the London Metals Exchange by Sumitomo Corporation and Yasuo Hamanaka over the period 1987-1996.

1999-Present: Dr. Hartman consulted with counsel and the testifying expert in the development of data and models needed to certify class and measure damages in a price fixing case involving the manufacturer (Mylan) of generic clorazepate and lorazepam.

1999-2001: Working as the testifying expert, Dr. Hartman analyzed liability arising from a variety of restrictive dealer arrangements implemented by Dentsply International Inc., a U.S. manufacturer of artificial teeth, to foreclose entry by rival manufacturers from the US dental-laboratory dealer network. Dr. Hartman developed and implemented methods to measure damages to the class of dental laboratories that purchased artificial teeth from Dentsply at prices above the competitive prices that would have obtained absent the restrictive dealer arrangements.

1999-2000: Working with a team of economists for the Federal Trade Commission, Dr. Hartman analyzed the pro-competitive and anti-competitive nature of settlement agreements between generic and pioneer drug manufacturers resolving patent infringement litigation arising from certification under Paragraph IV of the Hatch Waxman Act (Drug Price Competition and Patent Term Restoration Act). Particular settlements analyzed include the settlement between Abbott Laboratories and Geneva Pharmaceuticals regarding the drug Hytrin and the settlement between Hoechst Marion Roussel (Aventis) and Andrx Corporation regarding the drug Cardizem.

1999-2000: Working as the testifying expert for the class of purchasers of Nine West shoes, Dr. Hartman was asked to analyze liability and measure damages arising from an alleged conspiracy to raise and maintain the prices of women's shoes manufactured by the Nine West Group Inc. and sold by a variety of general merchandise retailers through their upscale retail department stores. The defendants in the case included Nine West Group Inc., Federated Department

Stores, Inc., Dayton Hudson Corporation, Lord and Taylor, Nordstrom, Inc., May Department Stores, Macy's, Bloomingdale's, Inc., and other general merchandise retailers.

2000: Working with the testifying expert, Dr. Hartman assisted in the analysis and estimation of economic damages to a Class defined as all smokers with 20-pack years each of whom contracted lung cancer which was substantially contributed to by cigarette smoking.

2000: Working with a team of economists, Dr. Hartman developed econometric models to analyze and measure the impacts of subject imports, non-subject imports and factor price changes upon the prices of structural steel beams during the period 1998-1999. The work was presented before the International Trade Commission.

2001: Working with a team of economists, Dr. Hartman developed econometric models to analyze and measure the impacts of subject imports, non-subject imports and factor price changes upon the prices of structural steel beams and during 2000. He also developed econometric models to analyze and measure the impacts of subject imports, non-subject imports and factor price changes upon the prices of cold rolled and hot rolled steel during the Period of Inquiry of 1997-1999. Both efforts were presented before the International Trade Commission.

2001-present: Working as the testifying expert, Dr. Hartman developed and submitted testimony in support of class certification of and the calculation of damages to the class of indirect purchasers of the anti-hypertensive drug, Hytrin, produced by Abbott Laboratories and the generic equivalent of Hytrin, generic terazosin hydrochloride, produced by Geneva Pharmaceuticals. The class alleges monopolization and violation of the Hatch Waxman Act (Drug Price Competition and Patent Term Restoration Act).

2001-Present: Working as consultant and testifying expert, Dr. Hartman has been retained by counsel to the classes of indirect or direct purchasers of a variety of branded pharmaceuticals (including but not limited to Augmentin, Bextra, Cipro (New York, California, U.S.), BuSpar, Celebrex, Vioxx, K-Dur, Taxol, Lupron, Relafen, Paxil, Neurontin, Remeron, Tamoxifen, Premarin and Wellbutrin) to analyze and submit testimony dealing with class certification, liability, market definition, damage calculations and settlement allocations arising from violations of the Hatch Waxman Act (Drug Price Competition and Patent Term Restoration Act) and related state-specific unfair competition statutes.

Dr. Hartman's testimony in this area has been relied upon (and cited thereto) for certification of end-payer consumer classes in the following matters:

- *In re: Terazosin Hydrochloride Antitrust Litigation*, United States District Court, Southern District of Florida, Case No. 99-MDL-1317-Seitz/Klein [Order Granting Indirect Purchaser Plaintiffs' Motions for Class Certification of State-Wide Classes, April 8, 2004]
- *In re Cipro Cases I and II*, D043543 (JCCP Nos. 4154, 4220), Court of Appeal, Fourth Appellate District, Division One, State of California [Decision affirming class certification not titled but marked as "Not to Be Published in Official Reports," Filed 7/21/04]
- *In re: Relafen Antitrust Litigation*, United States District Court, District of Massachusetts, Master File No. 01-12239-WGY [Memorandum granting certification for an exemplar class, May 12, 2004]

Dr. Hartman's testimony has been relied upon (and cited as necessary) for approval of proposed settlement allocations in the following matters:

- *In re: Lupron® Marketing and Sales Practices Litigation*, United States District Court, District of Massachusetts, MDL No. 1430, Master File No. 01-CV-10861-RGS [Memorandum and Order Approving Settlement and Certifying the Class, May 12, 2005]
- *HIP Health Plan of Florida, Inc., On Behalf of Itself and All Others Similarly Situated v. Bristol-Myers Squibb Co. and American Bioscience*, Case Number 1:01CV01295, United States District Court for the District of Columbia
- *In re Buspirone Antitrust Litigation*, MDL No. 1413, United States District Court for the

Southern District of New York

- *In re Relafen Antitrust Litigation*, United States District Court, District of Massachusetts, Master File No. 01-CV-12222-WGY
- *In re Remeron Antitrust Litigation*, United States District Court, District of New Jersey, Master Docket No. 02-CV-2007

2001: Working as consultant to counsel for various U.S. steel producers, Dr. Hartman worked with a team of economists to develop econometric models to analyze and measure the impacts of imports, demand and factor price changes upon the prices of domestically produced carbon steel flat products and carbon steel long products in the Section 201 hearings before the International Trade Commission. Dr. Hartman testified before the ITC in the hearings. The Commission decided in favor of most of the products subject to these analyses.

2001: Working as consultant to counsel for Nucor Steel Corporation, Dr. Hartman worked with a team of economists to develop econometric models to analyze and measure the impacts of imports, demand and factor price changes upon the prices of domestically produced carbon steel cold rolled products for preliminary hearings before the International Trade Commission.

2001-2002: Consulting to counsel for the Plaintiff Class, Dr. Hartman analyzed the targeting of youth by cigarette advertisements in the matter *in re Devin Daniels, et. al., v. Philip Morris Companies, Inc., et. al.*, Case Number 719446, coordinated with JCCP 4042.

2001-2003: Working as testifying expert, Dr. Hartman developed and presented statistical evidence analyzing the relative performance of a particular cardiovascular surgeon litigating the fact that his surgical privileges had been revoked as a result of incompetent surgical performance and results. He testified before an arbitration panel in the matter.

2003: Working as the testifying expert for Defendants, Dr. Hartman submitted testimony analyzing the allegation of racial discrimination on the part of Wells Fargo Home Mortgage, Inc. and Norwest Mortgage, Inc.

2003: Working as a consulting expert to counsel for the class of purchasers of graphite electrodes, Dr. Hartman developed econometric models to assess the impact of alleged antitrust violations.

2003: Working as the testifying expert, Dr. Hartman submitted affirmative and rebuttal testimony in support of the certification of the plaintiff class of direct purchasers of glyphosate-based and paraquat-based herbicides who are alleged to have been impacted and injured as a result of a horizontal price fixing conspiracy between the two largest producers of these herbicides.

2003: Working as a consulting expert for counsel to the class of direct purchasers, Dr. Hartman reviewed materials in a matter regarding antitrust allegations concerning the manufacture and sale of microcrystalline cellulose in the United States.

2003: Working as a consulting expert to counsel for a large electrical generation company, Dr. Hartman developed economic and econometric models to analyze the allegation that this electrical generation company participated in a conspiracy to manipulate prices of power sold in California.

2003: Working as the testifying expert, Dr. Hartman submitted testimony which analyzed and calculated the economic impacts and damages to the U.S. growers and quota holders of flue-cured and burley tobacco leaf caused by a price-fixing conspiracy among the major U.S. tobacco leaf buyers and cigarette manufacturers.

2004: Working as the consulting expert for the United States Department of Justice, Dr. Hartman critically analyzed the calculation of the economic damages borne by an electric power generation utility as a result of the breach of the Standard Contract with the U.S. Department of Energy to remove spent nuclear fuel in 1998. Dr. Hartman's analysis included a critical review and rebuttal of the models and data put forward by the utility's experts in the calculation of damages; the development and presentation of alternative and improved models and corrected data to more

accurately calculate damages; a critical review of econometric analyses put forward by one of the utility's experts; and a review of the economics of re-licensing existing nuclear generating facilities.

2004: Working as the testifying expert, Dr. Hartman submitted testimony in support of the certification of the class of purchasers of electrical carbon products who have been alleged to have been impacted and injured economically as a result of a price-fixing customer-allocation conspiracy of the major suppliers of such products in the United States.

2004: Working as the testifying expert, Dr. Hartman submitted testimony in support of the certification of the class of end payer purchasers of those pharmaceutical products produced by AstraZeneca, the Bristol Myers Squibb Group, the Johnson and Johnson Group, the Glaxo-Smith-Kline Group and the Schering Plough Group that were subject to an alleged scheme to fraudulently inflate their Average Wholesale Price (AWP), thereby fraudulently inflating the reimbursement rates paid by the Class members for those pharmaceuticals when their reimbursement rates were formulaically related to the AWP. Dr. Hartman is consulting on related litigation undertaken by the Offices of the Attorneys General for the states of New York and Connecticut.

2004-2005: Working as a consulting expert to counsel for a major electricity and gas utility holding company, Dr. Hartman developed models to evaluate allegations of affiliate abuse by the regulated gas distribution entities and the trading entities of the holding company. The alleged abuses concerned spot and forward gas markets in California.

2005: Working as the testifying expert for the United States Department of Justice, Dr. Hartman developed models to critically analyze the cost submissions to the U.S. Court of Federal Claims by the TVA for monetary damages alleged to have resulted from partial breach by the U.S. Department of Energy of the Standard Contract to remove spent nuclear fuel from TVA beginning in 2002. Dr. Hartman's analysis included a critical review and rebuttal of the models, data and cost analyses put forward by the utility and the development and implementation of alternative and improved models and corrected data to more accurately calculate costs attributable to the alleged partial breach.

**RECENT TESTIMONY OF RAYMOND HARTMAN
AT DEPOSITION, HEARING OR TRIAL**

1995

The Economic Effects of Repealing the Prime Time Access Rule: Impact on Broadcasting Markets and the Syndicated Program Market, report presented in informal hearings before the Federal Communications Commission, MM Docket No. 94-123, March 7, 1995

Gillam v. Abex, et. al., San Francisco Superior Court No. 966241, 1995 (deposition)

Trilogy Communications Inc. v. Times Fiber Communications & LPL Technologies Inc., United States District Court for the Southern District of Mississippi, Jackson Division, Civil Action No. J91-0542 (W)(S), 1995 (deposition)

1996

Hall v. Abex, et. al., San Francisco Superior Court No. 958853, 1996 (deposition)

Sowers v. Abex, et. al., San Francisco Superior Court No. 949184, 1996 (deposition)

1997

Hillenbrand v. INA/Aetna, Sacramento County Superior Court No. 519223, 1997 (deposition)

1998

Hillenbrand v. INA/Aetna, Sacramento County Superior Court No. 519223, 1998 (trial)

Trilogy Communications Inc. v. Pennie & Edmonds, LLP, et. al., United States District Court for the Southern District of Mississippi, Jackson Division, Civil Action No. CIV-3:97CV722BN (deposition)

Paper Systems Incorporated v. Mitsubishi Corporation; Mitsubishi International Corporation; Mitsubishi Paper Mills Ltd.; Elof Hansson Paper & Board, Inc.; Kanzaki Specialty Papers, Inc.; Oji Paper Co., Ltd.; and Nippon Paper Industries Co., Ltd. (Civil Action No. 96-C-959), consolidated with *Graphic Controls Corp. v. Mitsubishi Corporation; Mitsubishi International Corporation; Mitsubishi Paper Mills Ltd.; Appleton Papers, Inc.; Elof Hansson Paper & Board, Inc.; Kanzaki Specialty Papers, Inc.; Oji Paper Co., Ltd.; and Nippon Paper Industries Co., Ltd.* (Civil Action No. 97-C-412) and *Victor Paper Roll Products, Inc. v. Mitsubishi Corporation; Mitsubishi International Corporation; Mitsubishi Paper Mills Ltd.; Appleton Papers, Inc.; Elof Hansson Paper & Board, Inc.; Kanzaki Specialty Papers, Inc.; Oji Paper Co., Ltd.; and Nippon Paper Industries Co., Ltd.* (Civil Action No. 97-C-508), United States District Court for the Eastern District of Wisconsin (deposition)

1999

Joint Testimony of Seabron Adamson and Raymond Hartman on Behalf of The Massachusetts Attorney General in. re The Joint Petition of Eastern Enterprises and Colonial Gas Company for Approvals of Merger

Pursuant to G.L.c. 164 " 96 and 94, before the Department of Telecommunications and Energy, D.T.E. 98-128 (hearing)

Joint Testimony of Seabron Adamson and Raymond Hartman on Behalf of The Massachusetts Attorney General in re The Joint Petition of Boston Edison Company, Cambridge Electric Light Company, Commonwealth Electric Company, and Commonwealth Gas Company for Approval of Rate Plan Pursuant to G.L.c. 164 " 76 and 94, before the Department of Telecommunications and Energy, D.T.E. 99-19 (hearing)

2001

Oral testimony before the International Trade Commission regarding the impacts of imports, domestic demand and factor price changes upon the prices of domestically produced carbon steel flat products and carbon steel long products during the Section 201 Hearings (Inv. No. TA-201-073 (final))

2002

In re Terazosin Hydrochloride Antitrust Litigation, Case No. 99-MDL-1317 Seitz/Garber, consolidated, United States District Court for the Southern District of Florida, (deposition on affirmative and rebuttal testimony in support of class certification and deposition on affirmative testimony on damage analysis)

In re Buspirone Antitrust Litigation, United States District Court, Southern District of New York, MDL Docket No. 1410 (deposition on affirmative and rebuttal testimony on class certification)

Anne Cunningham and Norman Mermelstein, Individually and on Behalf of all Others Similarly Situated, v. Bayer AG, Bayer Corporation, Barr Laboratories, Inc, The Rugby Group, Inc., Watson Pharmaceuticals, Inc. and Hoechst Marion Roussel, Inc., Index No. 603820-00, Supreme Court of the State of New York, County of New York (deposition on affirmative testimony on class certification)

In re Ciprofloxacin Hydrochloride Antitrust Litigation, Master File No. 1:00-MD-1383, United States District Court for the Eastern District of New York. (deposition on affirmative testimony on class certification)

2003

In re Terazosin Hydrochloride Antitrust Litigation, Case No. 99-MDL-1317 Seitz/Garber, consolidated, United States District Court for the Southern District of Florida, (deposition on rebuttal testimony on damage analysis)

Anne Cunningham and Norman Mermelstein, Individually and on Behalf of all Others Similarly Situated, v. Bayer AG, Bayer Corporation, Barr Laboratories, Inc, The Rugby Group, Inc., Watson Pharmaceuticals, Inc. and Hoechst Marion Roussel, Inc., Index No. 603820-00, Supreme Court of the State of New York, County of New York (deposition on rebuttal testimony in support of class certification)

In re Ciprofloxacin Hydrochloride Antitrust Litigation, Master File No. 1:00-MD-1383, United States District Court for the Eastern District of New York. (deposition on rebuttal testimony in support of class certification)

Cipro Cases I and II, Judicial Council Coordination Proceeding Nos. 4154 and 4220 (Superior Court, San

Diego County) (depositions on affirmative and rebuttal testimony in support of class certification)

In re Relafen Antitrust Litigation, United States District Court, District of Massachusetts, Master File No. 01-CV-12222-WGY (depositions on affirmative and rebuttal testimony on class certification and affirmative testimony on damages)

Dr. Gregory Derderian, et. al., Plaintiffs, v Genesys Health Care Systems, et. al., Defendants, Case No. 99-64922-CK, State of Michigan, Circuit Court for the County of Genesee (testimony before arbitration panel)

In re S&M Farm Supply, Inc. v. Pharmacia Corporation; and Monsanto Company, Case No. 4:02CV518ERW, United District Court for the Eastern District of Missouri (deposition on affirmative testimony in support of class certification)

In re D. Lamar DeLoach, et. al., Plaintiffs, v. Philip Morris Companies, Inc., et. al., Defendants, in the United States District Court for the Middle District of North Carolina, Greensboro Division, Case No. 00-CV-1235 (depositions on affirmative and rebuttal testimony calculating damages)

2004

In re Ciprofloxacin Hydrochloride Antitrust Litigation, Master File No. 1:00-MD-1383, United States District Court for the Eastern District of New York (depositions on affirmative and rebuttal testimony calculating damages and affirmative and rebuttal testimony analyzing liability and market definition)

In re Lupron Marketing and Sales Practices Litigation, MDL No. 1430, CA No. 01-CV-10861, United States District Court, District of Massachusetts (deposition on affirmative testimony in support of class certification)

In re Pharmaceutical Industry Average Wholesale Price Litigation, United States District Court for the District of Massachusetts, MDL, No. 1456, CIVIL ACTION: 01-CV-12257-PBS (deposition on affirmative testimony in support of class certification)

2005

In re Lupron Marketing and Sales Practices Litigation, MDL No. 1430, CA No. 01-CV-10861, United States District Court, District of Massachusetts, (submission of written testimony at trial)

In re Tennessee Valley Authority, Plaintiff v. United States, Defendant, United States Court of Federal Claims, No. 01-249-C, (June 2, 2004 deposition and July 14-15, 2004 trial)

Lynne A. Carnegie v. Household International, Inc., Household Bank, f.s.b., successor in interest to Beneficial National Bank, Household Tax Masters Inc., formerly known as Beneficial Tax Masters, Inc., Beneficial Franchise Company, Inc., H&R Block, Inc., H&R Block Services, Inc., H&R Block Tax Services, Inc., H&R Block Eastern Tax Services, Inc., Block Financial Corp. and HRB Royalty, Inc., No. 98 C 2178, United States District Court for the Northern District of Illinois Eastern Division, (submission of written testimony and deposition on calculation of damages)

Attachment B

Attachment B: Materials Relied Upon

Manufacturer Data:

AstraZeneca Data:

- See Attachment G.1.d

Bristol-Myers Squibb Data:

- See Attachment G.2.d

GlaxoSmithKline Data:

- See Attachment G.3.d

Johnson & Johnson Data:

- See Attachment G.4.d

Schering-Plough Data:

- See Attachment G.5.d

Claims Data:

Blue Cross Blue Shield of Kansas City

- BCBS-KC data as provided by Dr. Gaier

Bates-Numbered Documents:

Insurer Contracts used as exhibits in the Declaration of Steven J. Young:

- HUM00839 – HUM00912
- HUM01151 – HUM01214
- HUM01867 – HUM01921
- KC0003265 – KC0003266

Discovery Documents:

- AZ 0670466-73
- AZ0004662-84
- AZ0004734-55
- AZ0009978-9991
- AZ0010334-7
- AZ0013206-9
- AZ0013233-5
- AZ0021798-802
- AZ0022281-94

- AZ0040464
- AZ0080407-11
- AZ0089616-25
- AZ0092152-62
- AZ0426670-4
- AZ0427246-65
- AZ0465663-4
- AZ0565611-14
- BMS/AWP/000071159-62
- BMS/AWP/00986726
- BMS/AWP/01109782
- BMSAWP/0011247-8
- ESI-277-00002066-77
- GSK-MDL-KY01-001684-7
- GSK-MDL-KY01-002225
- GSK-MDL-KY01-005532-36.
- GSK-MDL-KY01-007599
- GSK-MDL-KY01-008042-59
- GSK-MDL-KY01-009577-825
- GSKMDLKYTR01-0111126
- GSKMDLKYTR01-0111129-33
- GSKMDLKYTR01-0118005-17
- GSKMDLKYTR02-00170900-100
- GSKMDLKYTR02-0043706-7
- GSKMDLKYTR02-0048174-9
- GSKMDLKYTR02-0207877-82
- GSKMDLKYTR02-0219719
- GSK-MDL-ZN-01-048606-9
- GSK-MDL-ZN-01-049874
- GSK-MDL-ZN-01-049876
- GSK-MDL-ZN-01-057676-7
- GSK-MDL-ZN02-017931-2
- GSK-MDL-ZN-02-071651
- GSK-MDL-ZN-02-071790-1
- GSK-MDL-ZN02-072192
- GSK-MDL-ZN-06-007997
- MDL-KY01-001177-205
- MDL-OB100006781, 6789, 6810

Legal Documents:

Berndt, Ernst R., Report of Independent Expert Professor Ernst R. Berndt to Judge Patti B. Saris, *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, Civil Action No. 01-12257-PBS, February 9, 2005.

Gaier, Eric M., Declaration of Eric M. Gaier, *PhD in Support of Defendants' Opposition of Class Certification, In Re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, Civil Action No. 01-12257-PBS, October 25, 2004.

Gaier, Eric M., Sur-Reply Declaration of Eric M. Gaier, PhD in Support of Defendants' Opposition of Class Certification, *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, Civil Action No. 01-12257-PBS, January 21, 2005.

Hartman, Raymond S., Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification, *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, Civil Action No. 01-12257-PBS, September 3, 2004.

Hartman, Raymond S., Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification, *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, Civil Action No. 01-12257-PBS, December 16, 2004.

Hartman, Raymond S., Rebuttal Declaration of Raymond S. Hartman in Response to the Sur-Reply Declaration of Steven J. Young, *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, Civil Action No. 01-12257-PBS, March 9, 2005.

In re: Pharmaceutical Industry Average Wholesale Price Litigation, Memorandum and Order re: Motion for Class Certification, United States District Court, District of Massachusetts, MDL No. 1456, Civil Action No. 01-12257.

Patterson, Keith, Deposition, *In re Pharmaceutical Industry Average Wholesale Price Litigation*, June 28, 2005.

Rosenthal, Meredith, Liability Report of Dr. Meredith Rosenthal, *In re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, United States District Court for the District of Massachusetts, December 15, 2005.

United States of America v. TAP Pharmaceutical Products, Inc., Sentencing Memorandum of the United States, United State District Court for the District of Massachusetts, Eastern Division, Criminal Action, No. 01-CR-10354-WGY

Young, Stephen J., Declaration of Steven J. Young in Opposition to the Plaintiffs' Motion for Class Certification, *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, Civil Action No. 01-12257-PBS, October 25, 2004.

Young, Steven J., Sur-Reply of Steven J. Young in Opposition to the Plaintiffs' Motion for Class Certification, *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, Civil Action No. 01-12257-PBS, January 20, 2005.

Other Materials Relied Upon:

42 CFR 405.517, Revised October 1, 1996 and October 1, 2003

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Berndt, E.R. "The U.S. Pharmaceutical Industry: Why Major Growth in Times of Cost Containment?" *Health Affairs*, 20(2), 2001.

Besley, T. and Case, A., "Incumbent Behavior: Vote-Seeking, Tax-Setting, and Yardstick Competition," *American Economic Review*, 85(1), March, 1995.

Cooper, W.W., "The Yardstick for Utility Regulation," *Journal of Political Economy*, 51(3), 1943.

Department of Health & Human Services, Centers for Medicare & Medicaid Services, CMS Manual System, Pub. 100-04 Medicare Claims Processing, Transmittal 54, December 24, 2003.

Department of Health & Human Services, Centers for Medicare & Medicaid Services, CMS Manual System, Pub. 100-04 Medicare Claims Processing, Transmittal 352, November 3, 2004.

Department of Health & Human Services, Centers for Medicare & Medicaid Services, CMS Program Memorandum to Carriers, February 7, 2003.

Department of Health & Human Services, Centers for Medicare & Medicaid Services, Crosswalk Data from: <http://www.cms.hhs.gov/providers/drugs/asp.asp>.

Department of Health and Human Services, Office of Inspector General, "Appropriateness of Medicare Prescription Drug Allowances," OEI-03-95-00420, May, 1996.

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Hartman, Raymond S. and Doane, Michael "The Use of Hedonic Analysis for Certification and Damage Calculations in Class Action Complaints," *The Journal of Law, Economics and Organization*, Fall 1987.

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Medicare Payment Advisory Commission (MedPAC), Report to the Congress, "Variation and Innovation in Medicare", June 2003.

Plotkin, Irving H. "Total Rate of Return and the Regulation of Insurance Profits," Arthur D. Little Report, Presented at the May 1979 Meetings of the Casualty Actuarial Society, Chapter IV.

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http://www.cms.hhs.gov/manuals/104_claims/clm104index.asp.

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Attachment C

ATTACHMENT C

ALL INSURER CONTRACTS FOR PHYSICIAN – ADMINISTERED DRUGS USED AS EXHIBITS IN VOLS. II-A AND II-B TO THE DECLARATION OF STEVEN J. YOUNG USED AWP \pm % TERMS FOR DRUG REIMBURSEMENT RATE

Vol. II-B Tab.	Entity	Beginning Bates Range	Ending Bates Range	Description and Terms
21	Humana	HUM00839	HUM00912	Humana and Kansas City Oncology and Hematology Group "PHYSICIAN GROUP PARTICIPATION AGREEMENT AMENDMENT" dated 6/1/02. At HUM00841, the terms of the agreement provide: "1. For (HCPCS "J Codes" and Q0136) shown in the table below, payment will be at 110% of AWP or AWP listed in table below to be updated quarterly by GROUP." At HUM008843, additional terms provide: "Note: Any J Code not listed above pay at one hundred ten percent (110%) of AWP." Beginning at HUM00850 is attached the original agreement entitled: "PHYSICIAN GROUP PARTICIPATION AGREEMENT." The physician reimbursement drug rates lists at HUM00896 are based on varying percentages of AWP.
21	Humana	HUM01151	HUM01214	Humana "Physician Group Participation Agreement." Dated 2/1/03. At HUM01196, the contract terms provide: "Drugs to be reimbursed at current average wholesale price at date of service less sixteen percent (AWP-16%)"
21	Humana	HUM01867	HUM01921.	Undated/Redacted Humana "Physician Group Participation Agreement." At HUM0194, the terms provide for drug reimbursement AWP-16%.
27	BCBS, KC	KC0003265	KC0003266	Letter Agreement and Memo dated 5/1/00 for Chemotherapy Drug Pricing by Preferred Care Insured 115% of AWP (First DataBank); Preferred Care Blue Leased 110% of AWP (First DataBank); Preferred Care Blue Insured 100% of AWP; Commercial HMO 100% of AWP; and Medicare HMO 100% of AWP.

Attachment D

Attachment D

Selected Excerpts:

Medicare Claims Processing Manual Chapter 17 - Drugs and Biologicals¹

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Crosswalk to Old Manuals

10 - Payment Rules for Drugs and Biologicals

20 - Payment Allowance Limit for Drugs and Biologicals Not Paid on a Cost or Prospective Payment Basis

20.1 - MMA Drug Pricing Average Sales Price

20.1.1 - Online Pricing for Average Sales Price

20.2 - Single Drug Pricer (SDP)

20.3 - Calculation of the Payment Allowance Limit for DMERC Drugs

20.4 - Calculation of the AWP

20.5 - Detailed Procedures for Determining AWP and the Drug Payment Allowance Limits

20.5.1 - Background

20.5.2 - Review of Sources for Medicare Covered Drugs and Biologicals

20.5.3 - Use of Generics

20.5.4 - Find the Strength and Dosage

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10 - Payment Rules for Drugs and Biologicals

(Rev. 248, Issued 07-23-04, Effective: August 23, 2004/Implementation: January 1, 2005)

Drugs for inpatient hospital and inpatient skilled nursing facility (SNF) beneficiaries are included in the respective prospective payment system (PPS) rates except for hemophilia clotting factors for hospital inpatients under Part A. ... See Chapter 3 for instructions on billing inpatient hospital hemophilia clotting factors.

All hospital outpatient drugs are excluded from SDP because the payment allowance for such drugs is determined by a different procedure. Most drugs furnished to hospital outpatients are packaged under the outpatient prospective payment system (OPPS). Their costs are recognized and included but paid as part of the ambulatory payment classification (APC) for the service with which they are billed. Certain drugs, however,

¹ Taken directly from: http://www.cms.hhs.gov/manuals/104_claims/clm104index.asp; color emphasis in original.

are paid separately. These include chemotherapeutic agents and the supportive and adjunctive drugs used with them, immunosuppressive drugs, orphan drugs, radiopharmaceuticals, and certain other drugs such as those given in the emergency room for heart attacks.

The classes of drugs required to have “pass through” payments made under the Balanced Budget Refinement Act of 1999 (BBRA) have coinsurance amounts that can be less than 20 percent of the Average Wholesale Price (AWP). This is because pass-through amounts, by law, are not subject to coinsurance. The CMS considers the amount of the payment rate that exceeds the estimated acquisition cost of the drug to be the pass-through amount. Thus, the coinsurance is based on a portion of the payment rate, not the full payment rate.

Drugs are billed in multiples of the dosage specified in the HCPCS/NDC.

If the dosage given is not a multiple of the Health Insurance Common Procedure Coding System (HCPCS) code, the provider rounds to the next highest units in the HCPCS description for the code.

If the full dosage provided is less than the dosage for the code specifying the minimum dosage for the drug, the provider reports the code for the minimum dosage amount.

OPPS PRICER includes a table of drugs and prices and provides the intermediary (FI) with the appropriate prices.

Section 90 relates specifically to billing for hospital outpatients. The remainder of this chapter relates to procedures for pricing and paying DME recipients, and to beneficiaries who receive drugs under special benefits such as pneumococcal, flu and hepatitis vaccines; clotting factors, immunosuppressive therapy, self administered cancer and anti emetic drugs, and drugs incident to physicians services.

Drugs and biologicals not paid on cost or prospective payment basis have been paid based on the lower of the billed charge or 95 percent of the average wholesale price (AWP) as reflected in published sources (e.g., Red Book, Price Alert, etc.). Examples of drugs that have been paid on this basis include but are not limited to drugs furnished incident to a physician’s service, immunosuppressive drugs furnished by pharmacies, drugs furnished by pharmacies under the durable medical equipment benefit, covered oral anticancer drugs, and blood clotting factors. The Medicare Prescription Drug, Improvement, and Modernization Act (MPDIMA) of 2003 changed the basis for payment of drugs and biologicals not paid on a cost or prospective payment basis. Beginning January 1, 2004, through December 31, 2004, such drugs or biologicals are paid based on various standards specified in the statute, although the default standard is 85 percent of AWP. See §20, below for a full discussion of the basis for drugs in this category during 2004.

For services furnished on or after January 1, 2005, the payment allowance limit for drugs and biologicals is based on the Average Sales Price (ASP). This pricing file will be provided to contractors by CMS

20 - Payment Allowance Limit for Drugs and Biologicals Not Paid on a Cost or Prospective Payment Basis

(Rev. 131, 03-26-04)

AB-02-075, AB-02-174, PRM 2711.2 B.2, B3-5202, R1799B3

Prior to January 1, 2004, drugs and biologicals not paid on cost or prospective payment are paid based on the lower of the billed charge or 95 percent of the average wholesale price (AWP) as reflected in published sources (e.g., Red Book, Price Alert, etc.). Examples of drugs that are paid on this basis include, but are not limited to, drugs furnished incident to a physician's service, immunosuppressive drugs furnished by pharmacies, drugs furnished by pharmacies under the durable medical equipment benefit, covered oral anticancer drugs, and blood clotting factors.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, changed the basis for payment of drugs and biologicals not paid on a cost or prospective payment basis. For January 1, 2004, through December 31, 2004, such drugs or biologicals are paid as described below:

- The payment limits for blood clotting factors will be 95 percent of the AWP.
- The payment limits for new drugs or biologicals will be 95 percent of the AWP. A new drug is defined as an unlisted drug (not currently covered by a HCPCS code) that was FDA approved subsequent to April 1, 2003. A drug would not be considered new if: the brand or manufacturer of the drug changed; a new formulation of the vial size is developed; or the drug received a new indication.
- The payment limits for pneumococcal and hepatitis B drugs and biologicals will be 95 percent of the AWP.
- The payment limits for certain drugs studied by the OIG and GAO are based on the percentages of the April 1, 2003 AWP's specified on Table 1 below.
- The payment limits for infusion drugs furnished through an item of implanted durable medical equipment on or after January 1, 2004, will be 95 percent of the October 1, 2003 AWP.
- Drugs and biologicals not described above are paid at 85 percent of the April 1, 2003 AWP.

Payment limits determined under this instruction shall not be updated during 2004.

20.2 - Single Drug Pricer (SDP)

(Rev. 248, Issued 07-23-04, Effective: August 23, 2004/Implementation: January 1, 2005)

Effective January 1, 2003, contractors pay drug claims on the basis of the prices shown on the SDP files, if present.

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1. "HCPCS" Drug Pricing File

- a. CMS furnishes a SDP file that contains drugs identified by a code established by the Health Care Procedure Code System (HCPCS). This HCPCS drug-pricing file (HDPF) contains:
 - Every HCPCS drug code for every drug for which claims are submitted to local carriers (excluding DMERCs);
 - With respect to each such HCPCS code, the unit of measure by which such HCPCS code is defined;

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2. "Not otherwise classified" (NOC) Drug Pricing File

- a. CMS furnishes a NOC SDP file for drugs "not otherwise classified." This NOC drug pricing file (NDPF) contains:
 - With respect to every drug NOC under the HCPCS for which claims are submitted to local carriers (excluding DMERCs), the NDC code and drug name;
 - With respect to each such NDC code, the unit of measure by which such drug is covered;
 - With respect to each NOC drug, the Medicare allowed amount;

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3. The CMS furnishes a pricing documentation file (PDF) that contains only new drugs and biologicals for which a Medicare price has been established since the previous quarter:

- a. The data in the drug pricing file, i.e., each HCPCS code and its Medicare allowed amount;
- b. With respect to each HCPCS drug code, every product, as identified by its NDC code, that contains the same active ingredient as specified in the definition of the HCPCS code;
- c. With respect to those NDC codes used to determine the Medicare-allowed amount, an indicator to that effect;
- d. With respect to each such NDC, the price or prices used to determine the average wholesale price (AWP) of the product;
- e. With respect to each such price, an identification of the source(s) of the price; and
- f. With respect to each such source, the date, edition, and other information necessary and sufficient to enable CMS to verify the price.

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Except as specifically noted, each FI and carrier will:

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- Carriers continue to price drugs as outlined in §20.2 with respect to any drug that is not listed on the SDP files and with respect to any compounded drug that is not identified by a single NDC.
 - Report to the RO, on or before March 1 of each year, whether any drugs are being priced separately, including but not limited to NOC drugs. If one or more drugs are being priced separately, then the name of the drug, its NDC, the price determined, and the source used to price drug must also be included in the report.

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20.3 – Calculation of the Payment Allowance Limit for DMERC Drugs *(Rev. 248, Issued 07-23-04, Effective: August 23, 2004/Implementation: January 1, 2005)*

Payments for drugs billed to the DMERCs [local carriers] will be based on the implementation of the MPDIMA, beginning January 1, 2004, and will be paid at 85 percent of the AWP for HCPCS payment amounts based on the April 1, 2003 fee schedule. Exceptions to this calculation are as follows:

The payment limits for infusion drugs furnished through an item of durable medical equipment on or after January 1, 2004, will be 95 percent of the October 1, 2003 AWP.

- The payment limits for new drugs or biologicals will be 95 percent of the AWP. A new drug is defined as an unlisted drug (not currently covered by a HCPCS code) that was FDA approved subsequent to April 1, 2003. A drug would not be considered new if: The brand or manufacturer of the drug changed; a new formulation of the vial size is developed ; or the drug received a new indication.

The payment limits for certain drugs studied by the OIG and GAO are based on the percentages of the April 1, 2003 AWP's specified on Table 1 in §20 .

Payment limits determined under this instruction shall not be updated during 2004.

20.4 - Calculation of the AWP

(Rev. 248, Issued 07-23-04, Effective: August 23, 2004/Implementation: January 1, 2005)

Carriers must ensure that if any NDCs are added or deleted, the formulae are applied appropriately.

A separate AWP is calculated for each drug as defined by a HCPCS code. Within each HCPCS code there may be a single source or there may be many sources, or there may be no source.

- For a single-source drug or biological, the AWP equals the AWP of the single product.
- For a multi-source drug or biological, the AWP is equal to the lesser of;
 - The median AWP of all generic forms of the drug or biological; or
 - The lowest brand name product AWP.

A “brand name” product is defined as a product that is marketed under a labeled name that is other than the generic chemical name for the drug or biological.

After determining the AWP, carriers multiply it by 0.85 or 0.95, or other percentage, as applicable, and round to the nearest penny. This is the drug payment allowance limit. Carriers round it in accordance with standard rounding procedure. Part B coinsurance and deductible requirements apply.

In applying this procedure, carriers use the package sizes that are most commonly used for the most frequently administered dosage of the drug.

Intermediaries get drug prices from the carrier for drugs not listed on the Single Drug Pricer.

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20.5. 4 - Find the Strength and Dosage

(Rev. 248, Issued 07-23-04, Effective: August 23, 2004/Implementation: January 1, 2005)

Carriers use ampules, single dose and multiple dose vials and repacks to compare the strength and dosage. If multiple dose vials are used, carriers must determine how they are used, based on the strength indicator compared with the HCPCS code description (i.e., if the strength on the vial matches the HCPCS description, multi-dose vials should be used).

Carriers must determine which of the following conditions are true before pricing the drug:

1. The strength and dosage of the drugs in the price source match the HCPCS code and description.

Carriers calculate allowable reimbursements for drugs using “all” the NDCs for a given active drug ingredient and calculate a unit price that is associated with the HCPCS descriptor. If, for example, the HCPCS code descriptor specifies 50 ml and there is a 50 ml size shown in the Redbook or other source material, they may

use only the 50 ml size (and not use 10-5 ml vials) or may use all products that meet the strength based on strength and volume of the drug. In the latter case price per unit is calculated and then converted to the HCPCS units definition.

2. The strength and dosage from the HCPCS code description are not found in the price source.

Carriers use the closest dosage to the HCPCS definition without exceeding the dosage.

3. The strength and dosage in the price source do not include a generic form but do include a brand form.

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70 - Claims Processing Requirements - General (Rev. 1, 10-01-03)

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In addition to requirements applicable to all claims the following apply to drug claims.

- On claims to FIs the drug is identified by the appropriate HCPCS code for the drug administered and billed under revenue code 0636 unless specific instruction states otherwise;
- On claims to carriers the drug is identified by HCPCS code;
- All drugs, including Prodrugs, are reported to DMERCS by National Drug Code (see §80.1.2);
- Where HCPCS is required, units are entered in multiples of the units shown in the HCPCS narrative description. For example, if the description for the code is 50 mg., and 200 mg are provided, units are shown as 4;
- Where the NDC is required units are entered in multiples of the units shown in the NDC label description. For example, if the description for the code is 50 mg., and 200 mg are provided, units are shown as 4;
- If the units provided exceeds the size of the units field, e.g., requires over three characters to report, repeat the HCPCS or NDC code on multiple lines until all units can be reported;
- Covered administration codes for injections may be billed to the carrier and FI in addition to billing for the drug. The drug maximum payment allowance is for the drug alone. However, if payment is under a PPS, such as OPPS, the injection would be included in the APC rate.

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80 - Claims Processing for Special Drug Categories (Rev. 1, 10-01-03)

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80.1 - Oral Cancer Drugs (Rev. 1, 10-01-03)

Effective January 1, 1994, oral self administered versions of covered injectable cancer drugs furnished may be paid if other coverage requirements are met. To be covered the drug must have had the same active ingredient as the injectable drug. Effective January 1, 1999, this coverage was expanded to include FDA approved Prodrugs used as anti-cancer drugs. A Prodrug may have a different chemical composition than the injectable drug but body metabolizing of the Prodrug results in the same chemical composition in the body.

80.1.1 - HCPCS Service Coding for Oral Cancer Drugs (Rev. 1, 10-01-03)

The following codes may be used for drugs other than Prodrugs, when covered:

Generic/Chemical Name	How Supplied	HCPCS
Busulfan	2 mg/ORAL	J8510
Capecitabine	150mg/ORAL	J8520
Capecitabine	500mg/ORAL	J8521
Methotrexate	2.5 mg/ORAL	J8610
Cyclophosphamide *	25 mg/ORAL	J8530
Cyclophosphamide * (Treat 50 mg. as 2 units)	50 mg/ORAL	J8530
Etoposide	50 mg/ORAL	J8560
Melphalan	2 mg/ORAL	J8600
Prescription Drug chemotherapeutic NOC	ORAL	J8999

Each tablet or capsule is equal to one unit, except for 50 mg./ORAL of cyclophosphamide (J8530), which is shown as 2 units. The 25m and 50 mg share the same code.

Note: HIPAA requires that drug claims submitted to DMERCs be identified by NDC.

80.1.2 - HCPCS and NDC Reporting for Prodrugs (Rev. 136, 04-09-04)

FI claims

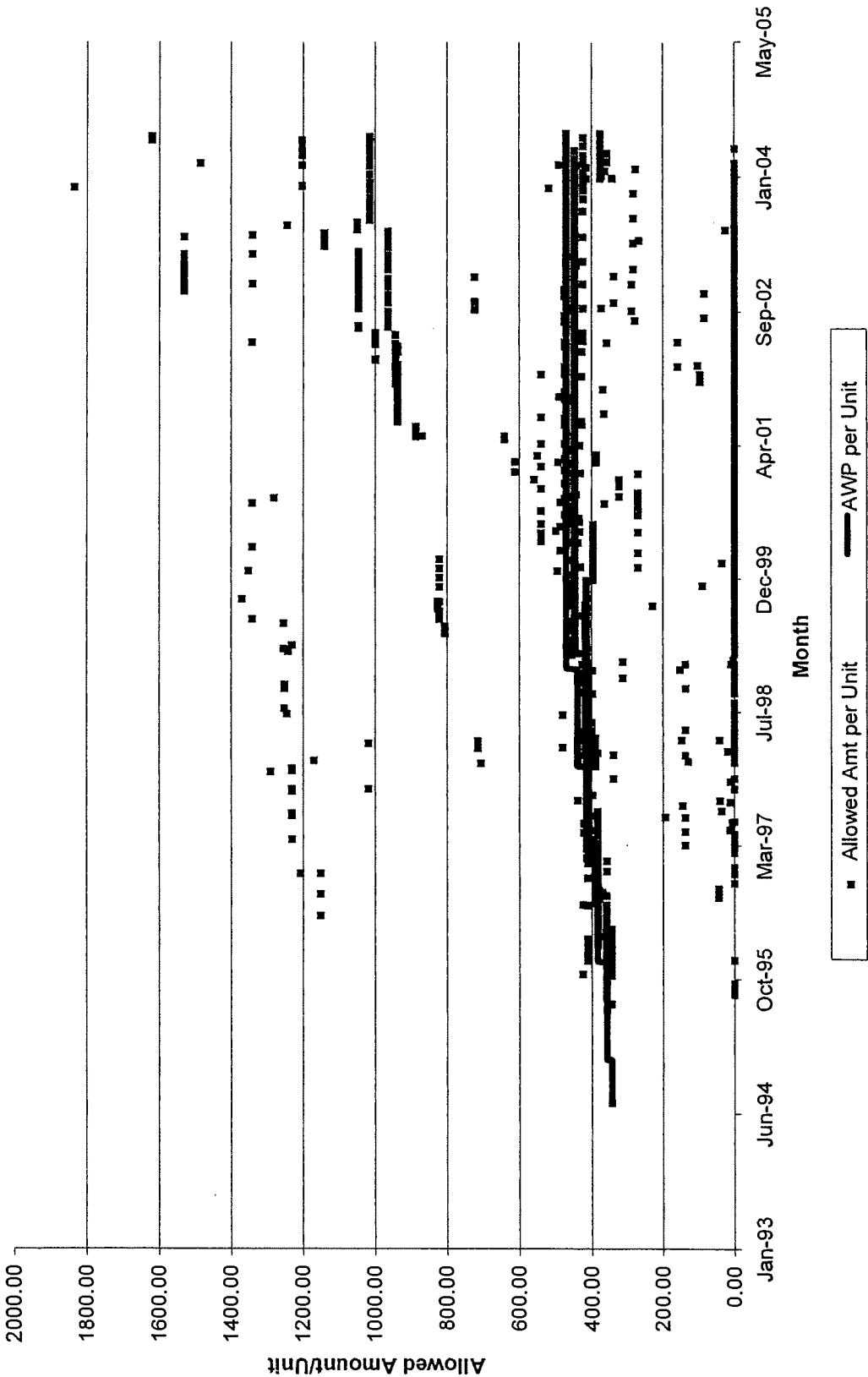
For oral anti-cancer Prodrugs HCPCS code J8999 is reported with revenue code 0636.

DMERC claims

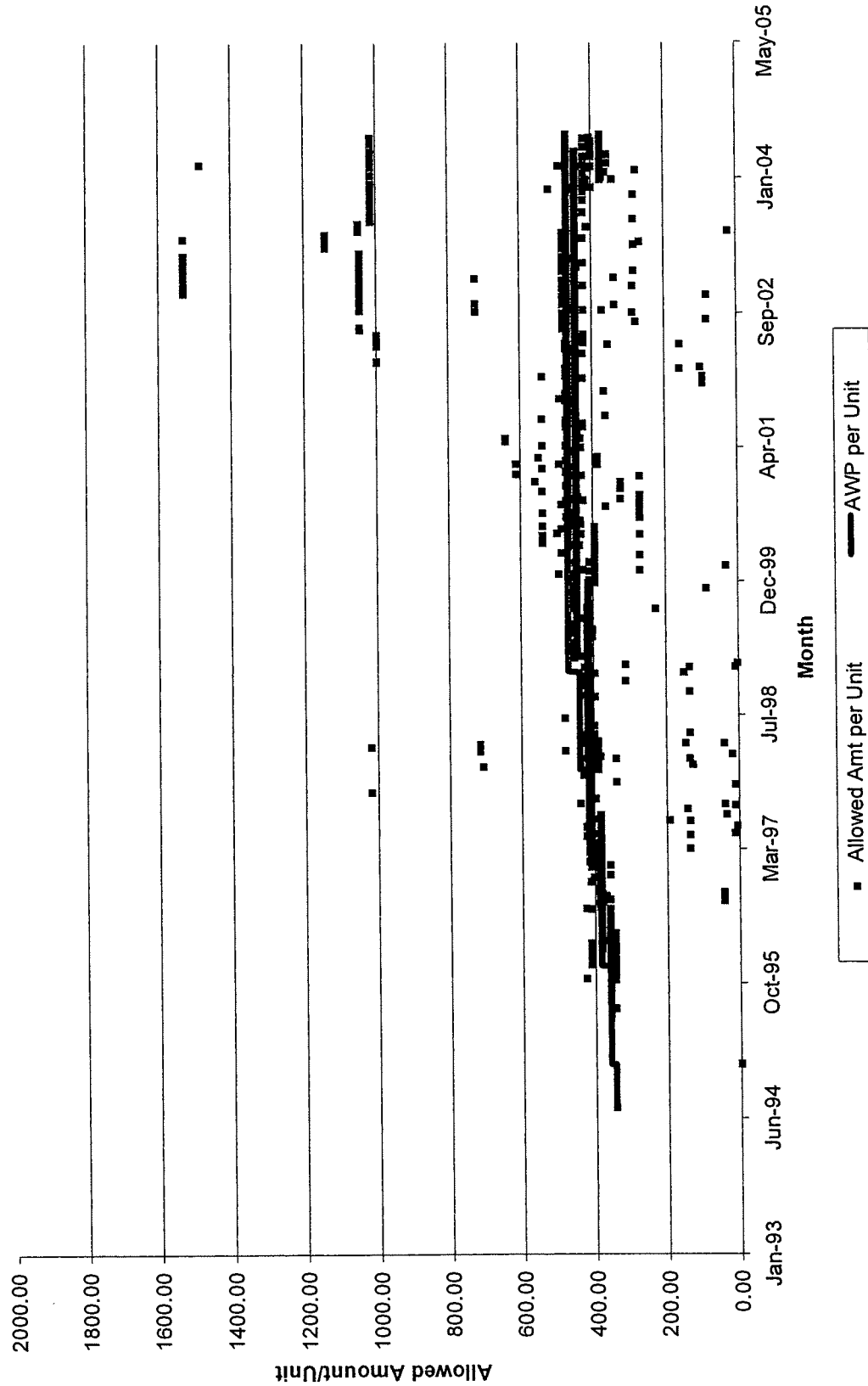
The supplier reports the NDC code on the claim. The DMERC converts the NDC code to a "WW" HCPCS code for CWF. *As new "WW" codes are established for oral anti-cancer drugs they will be communicated in a Recurring Update Notification.*

Attachment E

Attachment E.1: Blue Cross Blue Shield of Kansas City Zoladex Reimbursement (J9202)
NDC 00310-0960-36



Attachment E.2: Blue Cross Blue Shield of Kansas City Zoladex Reimbursement (J9202)
NDC 00310-0960-36



Attachment F

Attachment F: Summary of Selected Discovery Materials

Glaxo: ZOFRAN

Zofran is an anti-nausea medication used with chemotherapy, radiation or post surgery. While it has no generic equivalents, SmithKline's Kytril and Aventis' Anzemet (both brand-name drugs) are therapeutically similar and compete with Zofran. Zofran entered the market in 1991, Kytril in 1994 and Anzemet in 1997. After Glaxo and SmithKline merged, Kytril was divested from the newly formed company.

Glaxo understood what the AWP/ASP spread meant and how it could be used to compete with Kytril as discussed by this letter sent to T. Proctor, Glaxo's Senior VP, General Counsel and Secretary.

"..., we would like to draw your attention to reports we are receiving from our field force regarding reimbursement issues. In an apparent effort to increase reimbursement to physicians and clinics, effective 1/10/95, Glaxo increased AWP for Zofran by 8.5%, while simultaneously fully discounting this increase to physicians. The latter was accomplished by a 14% rebate available to wholesalers on all non-hospital Zofran sales of the multi-dose vial. The net effect of these adjustments is to increase the amount of reimbursement available to physicians from Medicare and other third party payors whose reimbursement is based on AWP. Since the net price paid to Glaxo for the non-hospital sales of the Zofran multi-dose vial is actually lower, it does not appear that the increase in AWP was designed to increase revenue per unit to Glaxo. Absent any other tenable explanation, this adjustment appears to reflect an intent to induce physicians to purchase Zofran based on the opportunity to receive increased reimbursement from Medicare and other third party payors. In fact, we have had numerous verbal reports from the field concerning Glaxo representatives who are now selling Zofran based on the opportunity for physicians to receive a higher reimbursement from Medicare and other third-party payors while the cost to the physician of Zofran has not changed." [Source: Letter from U. Bartels, SmithKline Beecham to T. Proctor, Senior VP, General Counsel and Secretary, Glaxo Inc. 2/22/95, GSK-MDL-KY01-005532-36.]

In addition, Glaxo understood that there could be legal and other negative ramifications of manipulating the spread.

"Contracting directly with the Oncology clinics could put Glaxo Wellcome in the Justice Department's spotlight by lowering the acquisition price on Glaxo Wellcome products purchased by these clinics without lowering the NWP." [Source: 1997 Oncology Clinic Contracting Strategy, at GSK-MDL-ZN02-072192.]

"If Glaxo chooses to increase the NWP and AWP for Zofran in order to increase the amount of Medicaid reimbursement for clinical oncology practices, we must prepare for the potential of a negative reaction from a number of quarters. Some likely responses: 1) Press: Glaxo's health care reform messages stressed the importance of allowing the marketplace to moderate prices. On the surface, it

seems that in response to the entrance of a competitor in the market, Glaxo has actually raised its price on Zofran – perhaps twice in one year. How do we explain that price increase on a drug that is already been cited in the press as one of, if not the most expensive drug on the hospital formulary? If we choose to explain the price increase by explaining the price strategy, which we have not done before, then we risk further charges that we are cost shifting to government in an attempt to retain market share.” ... “Is the industry helping to moderate health care costs when it implements policies that increase the cost of pharmaceuticals to government?” [Source: Zofran pricing recommendation considerations, GSK-MDL-ZN-01-057676-7.]

Glaxo understood the value and importance of the spread for physician-administered drugs.

“Physician reimbursement for the administration of intravenous oncology drugs is based on the spread between acquisition cost and the AWP. The typical spread between the List Price and the AWP in the industry is either 16 2/3% or 20%. The majority of agents in the oncology market carry a 20% AWP. This allows the oncologist to be compensated for the cost of the intravenous drug administered as Medicare reimburses at 80% of AWP. The administration of intravenous agents in the outpatient or clinic setting is almost exclusive to the oncology practice. SKB’s clinic promotion has been based on a therapeutic equivalency campaign with significant reimbursement advantages in favor of Kytril. The current reimbursement spread favors Kytril at \$18.80 per single dose vial compared to Zofran at \$-0.89 per 32mg dose per patient. ... Because Kytril is available in a single dose prescription, the complete vial may be billed for reimbursement. Zofran, as a multi-dose prescription, may only be billed on a milligram basis for the dose administered. Kytril carries a 20% spread between List Price and AWP compared to Zofran which carries a 16 2/3% spread providing SKB with a significant advantage in the clinic setting with respect to reimbursement.” [Source: Memo from D. Cory to S. Strotsky, dated 10/31/94, Subject: Pricing Committee Recommendation, GSK-MDL-ZN-01-048606-9.]

“... Kytril is using the Medicare reimbursement advantage over Zofran to increase its market share in the clinics ... This spread is the driving factor in Kytril’s higher market share in the clinics.” [Source: Zofran/Kytril Market Share Update GSK-MDL-ZN-06-007997.]

Rationale for proposed 1996 price increase for Zofran: “- Improves the competitive position of Zofran in the clinic market. Zofran clinic reimbursement spread will increase by \$7.31 to \$22.77 for a 32 mg dose from the multidose vial. - Increases the Zofran Injection 4 mg unit dose vial price to parity with the 40 mg multidose vial presentation on a per milligram basis. This will assist product management in establishing a unified pricing strategy for the brand. States can base Medicare reimbursement on the lowest published AWP/MG. By pricing the two presentations at parity, the possibility of States using the lower AWP to reimburse the clinics will be eliminated.” [Source: Proposed 1996 Price Increase for Zofran, GSK-MDL-ZN02-017931-2.]

Glaxo understood that without an effective competitor they did not have to manipulate the spread.

“Zofran is a novel agent with a safety and efficacy profile exceeding all other antiemetic products. Zofran has achieved the ideal position of market leader with no effective competitor. As a result, the price of Zofran should not be lowered to increase market share either on a local or national level.” [Source: Zofran Pricing Strategy, GSK-MDL-ZN-01-049874.]

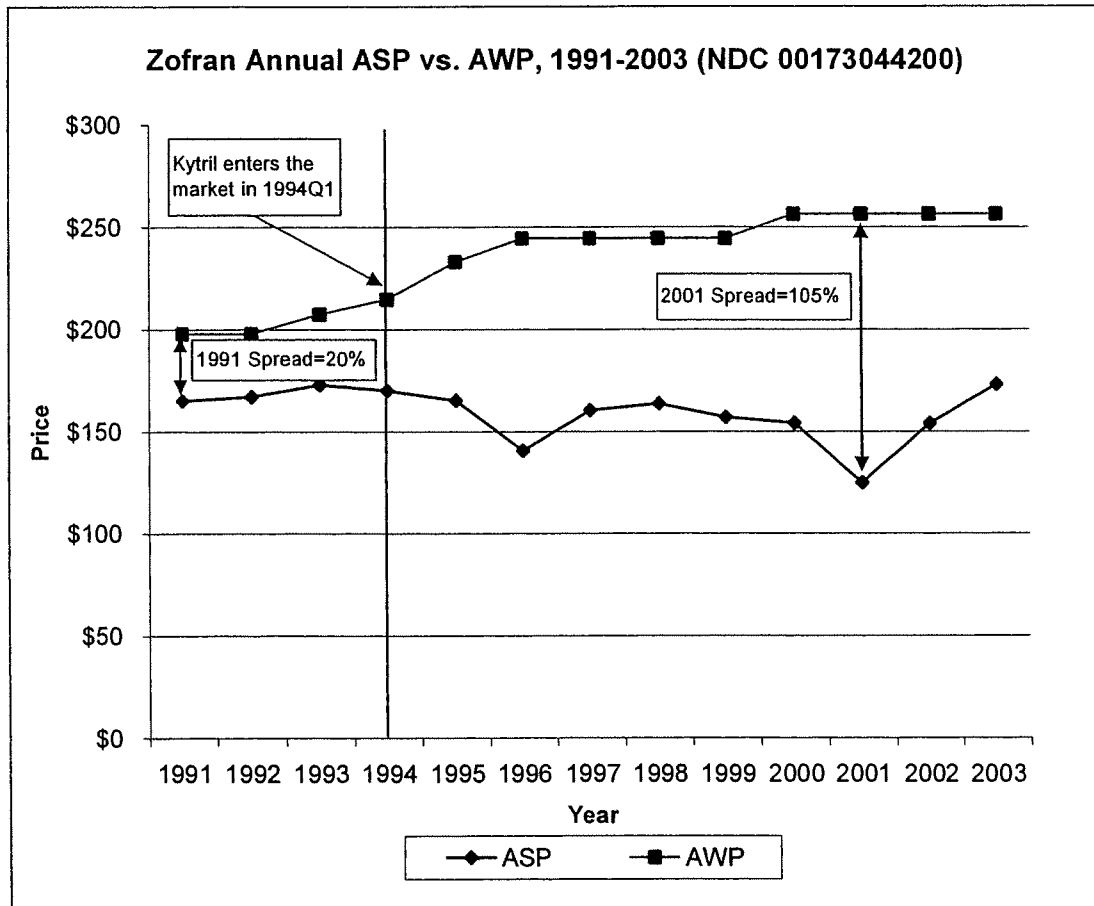
However, once Kytril entered the picture, Glaxo understood that in order to maintain their market share, they would have to compete on price. They chose to compete on price by manipulating the spread.

“Price protection should not be offered to institutions for more than one year prior to the introduction of Kytril. This will allow us to maintain control over profitability and pricing flexibility in anticipation of new competitive product introductions” ...“Once Kytril enters the market, obviously Zofran’s share will decline. At that time, we will need to establish a defensive bidding strategy that works to preserve the pricing structure.” [Source: Zofran Pricing Strategy, GSK-MDL-ZN-01-049876.]

“Increase Zofran marketing efforts to the outpatient services segments (office-based practices and clinics). This segment represents a significant growing portion of the overall Zofran market.” ... “Recommendation: Increase the price on Zofran IV by 3.5 % and price protect all contractual accounts.” ... “Rationale: ...— Create a higher benchmark price prior to Kytril’s introduction into the market. — Provide higher reimbursement levels to clinic-based physicians.” [Source: Zofran IV Pricing Strategy, fax date of 11/23/93, GSK-MDL-ZN-02-071651.]

In re upcoming 3.5% increase on Zofran injection: “... in the interest of cost containment Glaxo would like to provide an option to your all-important clinic customers. Your clinic customers may avoid this price increase by signing a contract with Glaxo. ... These agreements offer two substantial benefits to our customers who desire to participate. First is a reduction in the price of a product they use on virtually every patient receiving emetogenic cancer chemotherapy, and secondly, a higher AWP for reimbursement purposes, increasing the profitability of this high-volume product.” [Source: Memo from C. Pelzel, Director of Marketing to L. McLeod, M. Puccie, Cerenex and Hospital Regional Directors, dated of 11/24/93, GSK-MDL-ZN-02-071790-1.]

In fact, the data show that once Kytril became an active competitor, Glaxo, increased their AWP while at the same time decreasing their ASP. This increased their spread and allowed them to effectively market Zofran to physicians based on the spread which was much higher than their 20% spread prior to Kytril's entry. This is clearly illustrated in the figure below which shows Glaxo's ASP for a popular Zofran NDC and its corresponding published AWP.



SmithKline: Kytril

Kytril like Zofran is an anti-nausea medication used with chemotherapy, radiation or post surgery. While it has no generic equivalents, Zofran and Anzemet (both brand-name drugs) are therapeutically similar and compete with Kytril. Zofran entered the market in 1991, Kytril in 1994 and Anzemet in 1997.

Smithkline understood what the AWP/ASP spread meant and how it could be used to compete with Kytril as discussed by this letter sent to T. Proctor, Glaxo's Senior VP, General Counsel and Secretary.

“Moving forward we acknowledge the need for identifying strategies for continued and enhanced product growth. Our target customers are a small group of easily identified physicians, nurses, pharmacists, distributors, etc.” (at GSK-MDL-KY01-008046). ... “Prior to the introduction of Zofran in February, 1991, 70% of chemotherapy was administered on an inpatient basis. In spite of there being no breakthroughs in development of anti-neoplastic therapies, there has been a significant shift toward outpatient treatment ... The trend toward outpatient administration has created many new variables in the marketing equation for chemotherapy-associated products: 1. Office claims administrators are playing an increasing role in drug selection between two therapeutically equivalent products based on financial implications. In the hospital, drug cost is a key factor in product selection because reimbursement is based on a fixed price DRG, and drug cost directly competes with the profit flow to the hospital. In the outpatient setting, profit reflects the reimbursement allowance less the cost of the drug. So claims administrators are focused on maximizing that difference between reimbursement and cost. To the extent a product has no or delayed reimbursement by payers, that product will not likely be used particularly if the competing product is covered. Zofran is fully covered. Kytril is gaining coverage but has significant hurdles primarily government bureaucracy which precludes its unconditional acceptance in the outpatient setting. ...” [Source: US Marketing Strategic Plans, 1995-1997, SmithKline Beecham Pharmaceuticals, GSK-MDL-KY01-008042-59.]

A slide showing AWP and WACs in a Kytril meeting overhead presentation has the following note: “WAC and AWP are not customer acquisition cost” (at GSK-MDL-KY01-001179). Another slide in the packet subtitled “Price Strategy” says: “-Prices are low enough to claim ‘bragging rights’ without initiating a market-destabilizing price war – AWP is high enough to provide an attractive reimbursement margin to customers – Moderate list price advantage disguises true customer acquisition cost advantage” (at GSK-MDL-KY01-001180). [Source: Memo from E. Vick to D. Pernock and E. Posner, March 7, 1994, GSK-MDL-KY01-001177-205.)

A document shows a price comparison between Kytril and Zofran: Profit is shown based on the difference of “Oncology Cost” and “AWP” ranges from \$36.05 for Kytril 0.7 mg to \$80.94 for zofran 32 mg Bag. [Source: Dicke Van Thiel/Rich Francovitch - Kytril Issues, June 5, 1996, GSK-MDL-KY01-001684-7.]

In addition, Smithkline understood that there could be legal and other negative ramifications of manipulating the spread.

“I am recommending that we do NOT take a price increase of any kind in March and hold off until 4Q of this year to re-evaluate a potential price increase. Reasons are as follows:[...] 2. Due to greater government focus on injectable drug pricing in the oncology clinic setting, it is wise for SB to further space the timing between price increases on Kytril. If, for example, SB were to raise the price of Kytril in November of this year, a solid 18 months would have passed since the last price increase.” [Source: Letter from Pearl Pugh to Kevin Lokay, 1/27/00, GSKMDLKYTR02-0043706-7.]

“What the reps are asking the physicians to do is to try and beat Medicare out of another \$10 by giving the 32mg pre-filled bag even though it is the same product as in the multi ----- vile [sic]. And, the pre-filled bag actually costs \$5-\$10 less than the 32mg dose out of the ----- vile [sic]. Instead of using the J code that is already established for Zofran 32mg dose, they are asking them to use a miscellaneous J code and then submit it to be looked at manually. They are basically asking the physicians to do something that is unethical” (at GSK-MDL-KY01-009578). “While Glaxo did have a price increase, they also increased their discount back to the Oncology suppliers, so while the AWP has gone up, the price given to the oncology supply houses stayed the same. In effect, what Glaxo is doing is increasing the spread between what the doctors will pay for the drug and what they will be reimbursed for through Medicare. They are taking a risk by doing something like this. The attorney generals’ office people are investigating companies that are doing these things. So, while Glaxo has had an artificial increase, increase AWP but not increase the price, what we have is a real price increase. However, since all the oncology houses knew this was coming they all loaded up – the doctors won’t see this \$122 price for 2 or 3 months” (at GSK-MDL-KY01-009580). “We are trying to send a message to Glaxo that we have a price increase but we are not going to increase our price back to the supplier. We hope that they will respond to our message by changing their discount. We would like to see them bring their discounts down to around 14%. If Glaxo does not respond – and it negatively effects [sic] our sales – we will increase our discounts to the supply houses, although we hope it doesn’t come to something like that. We don’t think this is that much of a price driven decision any longer. Kytril is cheapest in the hospitals but, traditionally, our market share has been higher in the clinics, yet they are paying more in the clinics. We have to get people ... on the benefits of the product; the easier administration, better compatibility, lower incidence of side effects and not to try and sell strictly based on cost alone” (at GSK-MDL-KY01-009581). [Source: Minutes, Kytril Team Meeting, March 28, 1994, GSK-MDL-KY01-009577-825.)

SmithKline understood the value and importance of the spread and how to effectively use it to compete against Zofran.

“Increasing the price does not put Kytril at a competitive disadvantage because over 80% of the Kytril business is contracted and therefore protected. Due to the nature of the current environment, we are not trying to compete solely on price anyway (as this would accelerate the devaluation of the market) but rather on the

differentiating features of Kytril, particularly around safety and dosing/administration benefits. Market share for Kytril is not expected to decrease due to a price increase.” [Source: Recommendation from Pearl Pugh to Kevin Lokay, 4/23/99, GSKMDLKYTR02-0207877-82.]

“Kytril will be priced at WAC less 12% (116.86), which is equivalent to 27mg of Zofran.” [Source: Memo from D. Permock and E. Posner to H. Pien, March 1, 1994, GSK-MDL-KY01-002225.]

“Effective March 7, 1996 Glaxo increased the Wholesale Acquisity Cost (WAC) and Average Wholesale Prices (AWP) of Zofran 4.9%. At the same time, Glaxo also increased their rebate to keep the Actual Acquisition Cost (AAC) of Zofran the same. What this means is that Glaxo has increased the profit potential for physicians by raising the amount that physicians should bill for the drug and by keeping the cost the same.” [Source: Letter from B. Boate, Kytril Special Projects, 3/11/96, GSK-MDL-KY01-007599.]

“When prices for SB products were increased in August there was no increase taken for Kytril. A price increase on Kytril would contribute net dollars to the bottom line without leaving Kytril at a competitive disadvantage. Therefore I am requesting a 4.5% price increase for all forms of Kytril. While the majority of Kytril sales are under contract, a 4.5% price increase put in to effect October 30 would contribute approximately \$423M incremental net sales in 1998. With an additional 5% price increase effective 7/1/99 an additional \$1,241M in net sales could be realized in 1999. At the same time this should not disadvantage Kytril compared to its competitors. [Currently, Kytril’s contracted clinic and oncology group business (\$54MM) is competitively disadvantaged because SB does not pay admin fees to Oncology Supply Houses for facilitating the contracts between SB and contracted customers. We are considering altering this policy in 1999; the 1999 price increase mentioned above would more than fund this impact (\$890M).] When purchased through the oncology supply houses the price of Kytril for a 1 mg IV dose would become more expensive than a 32 mg IV dose of Zofran, however, using weight based dosing in which the average dose should be approximately 0.7 mg Kytril would maintain a price advantage. Kytril IV currently does not have a price advantage compared to Anzemet, however based on Kytril’s more favourable safety profile and well established efficacy in preventing chemotherapy induced nausea and vomiting, a higher price for a better product is justified. For those customers selecting an antiemetic purely based on price they would have switched to Anzemet already.” [Source: Recommendation from Rich Francovitch to Kevin Lokay, 10/15/98, GSKMDLKYTR02-0048174-9.]

“Other Contracting Options

- Reduce *Kytril’s* price to Wholesalers/Supply Houses (currently \$125/\$65]
- Maintain *Kytril’s* price to Supply Houses, but increase WAC and AWP to give customers a competitive spread
- Maintain *Kytril’s* price to Supply Houses, but issue suppliers free goods based on a percentage of the dollar volume sold through SB contracted accounts, enabling *Kytril* and suppliers to better track contracted sales

- Provide a (2%) promotion fee to Wholesalers/Supply Houses to incent them to proactively market *Kytril* to their customers”

[Source: *Kytril* Loyalist Contracting Proposal, 3/13/98, GSKMDLKYTR01-0111126.]

“Contracting with *Kytril* ‘Loyalists’ Objectives ... To reward loyal *Kytril* clinics and solidify future business through contracting and maintaining a competitive spread after *Kytril*’s change in J code.” [Source *Kytril* Loyalist Contracting Strategy, 3/20/98, GSKMDLKYTR01-0111129-33.]

“Essentially, the 5-HT₃ market has become extremely competitive, leaving market share capture as the main avenue for growth.” [Source: 2000 Tactical Plan, GSKMDLKYTR01-0118005-17.]

“Medicare reimbursement will change, potentially reducing clinics’ profit incentives. Today’s AWP-5% reimbursement will change to either AAC+5% or AGP tomorrow.

- Today, the ‘winner’ creates the largest profit spread for clinics. Tomorrow, the ‘winner’ in AAC+5% scenario will still be the competitor who creates the largest profit spread for clinics.
- In tomorrow’s APG scenario, the ‘winner’ is the low-cost provider. Clinics will rapidly shift to oral therapy and will send patients to hospitals and retail outlets for chemotherapy and antiemetics.
- Medicare and local carriers will all gradually recommend oral therapy as first-line treatment.
- Supportive care products will continue to be reimbursed and included under ‘cancer carve-outs”

[Source: 1999 *Kytril* Situation Analysis Update, GSKMDLKYTR02-00170900-100.]

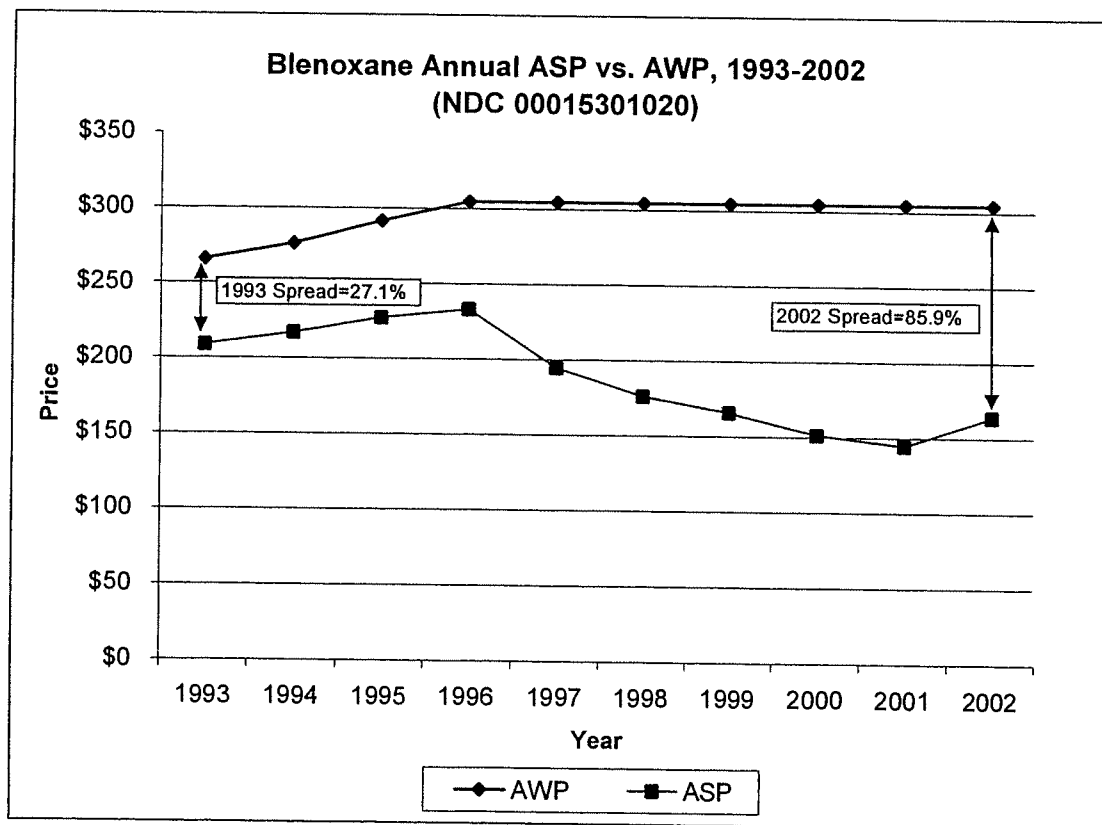
“I don’t think that there are any loyalist contracts at a \$100 price and I am not sure that we want to start now despite all the pressures we are facing from Anzemet. We have made the rare exception of approving a \$103 price for clinics with high volume and strategic positioning. Do you think that the \$105 price would be sufficient to maintain the business? If not, I am willing to go with a \$103 price for this particular customer if they can maintain a certain level of market share. By the way, what is their market share?” [Source: Email to Douglas Hartline from Pearl Pugh, 04/05/99, GSKMDLKYTR02-0219719.]

BMS: Blenoxane

Blenoxane is a chemotherapy drug for cancer including lymphomas and testicular cancers. There are generics for Blenoxane. The first generic entered in 1996. It is interesting to note that this generic's AWP was almost identical to that of the brand's generic. The generic AWP's were not significantly lower than the brand's AWP until other generics entered in 2000.

Discovery materials confirm that BMS was pricing Blenoxane significantly below their WLP (wholesale list price, which is commonly called WAC). For example, a memo from M. Barnard to G. Seymour, dated January 10, 2003 summarizes the discount at 61-62% off of WLP for the 15 mg dosage and 65-66% for the 30 mg dosage for the 3rd and 4th quarters of 2002. [Source: BMS/AWP/000071159-62]

The data show that at the time of the first generic, the BMS spread for Blenoxane increased substantially. BMS maintained this spread by offering large discounts off of their WLP prices hence increasing the spread available to physicians. Note that BMS increased its AWP at the time of the introduction of the first generic in 1996. It maintained its AWP listing; however, it manipulated the spread by significantly increasing its discounts resulting in low ASPs.



Although, BMS acknowledges that "AWP is the most common reimbursement mechanism used in the marketplace," it also states that "BMS does not set AWP for its' products. Third

parties set AWP based on company labeler code and wholesaler surveys” (see BMS/AWP/00986726). However, copies of letters sent directly to Medispan, First Data Bank by BMS clearly show that they are telling these AWP publishers to increase their AWP from 20.5% to 25% (see BMSAWP/0011247-8). In addition, because AWP is directly related to WAC (WLP), whenever BMS reported a WAC price to these publishers they were in effect setting the AWP. BMS understands that AWP affects “the way that customers view the cost of our products” (BMS/AWP/01109782).

AstraZeneca: Zoladex

Zoladex is LHRH (luteinizing hormone-releasing hormone) used as to treat prostate cancer. Lupron is a therapeutically similar chemical.

AstraZeneca actively used the spread to market its Zoladex drug to physicians so that physicians could maximize their return to practice. Discovery materials and deposition testimony confirm this.

“ ... [T]he Return to Practice that can be realized via the purchase of LHRH agonists is the primary driver behind this market. Return to Practice is enhanced by widening the margin between the published price and the acquisition cost. This can be accomplished through several pricing manipulations:

- 1) Increase the AWP
- 2) Decrease the acquisition cost relative to the AWP, or
- 3) Both 1 and 2.

In order to maximize the Return to Practice, and to maximize our competitive position, it is recommended that we exercise option #3 from above by implementing a differential price increase. Furthermore, in order to allow Zoladex to be competitive with Lupron in the top tier of accounts, it is recommended that ... we **create a discounted tier of 24% for purchases in excess of 192 depots (32 cases)**. The net result of these two pricing actions is that purchases of Zoladex will result in a **more favorable Return to Practice than Lupron at all purchase volumes above 6 depots.**” [Source: Internal Memorandum from Keith Patterson to Chris Iacono, November 20, 1995 regarding Zoladex Pricing Strategy, AZ0080407-11]

Keith Patterson who was a product manager at Zeneca and had responsibility for Zoladex defines return to practice as “It’s ... the amount of money that a physician can make after paying for a pharmaceutical product and ... being reimbursed...for their expenses. It’s their cost – the difference between their cost and their reimbursement rate.” [Source: Deposition transcript of Keith Patterson, June 28, 2005, *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, p. 58].

In re whether “return to practice, ... was a basis upon which Zeneca sold Zoladex to physicians?” [p. 60] Patterson responds: “To physicians who treated patients under Medicare Part B, it was one of several promotional platforms.” [p. 61] Patterson confirms that “Return to practice became ... an emphasis for the sale of Zoladex” [p. 63] and that “The program was implemented in May of 1994, and sales increases were observed after that point.” [p. 64] “That our primary client base, the urologists, placed a high level of importance on the financial returns that they received from prescribing Lupron. It was a significant driver in the marketplace.” “They [AZ salespeople] requested that an – an equal opportunity for our customers to – to realize return as they would for Lupron; level the playing field.” [p.115-116] [Source: Deposition transcript of Keith Patterson, June 28, 2005, *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456]

Patterson states that maintaining the acquisition price while raising the AWP “would be one way of increasing the spread between the AWP and the

acquisition cost.” [Source: Deposition transcript of Keith Patterson, June 28, 2005, *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, p.189]

AstraZeneca understood what the AWP/ASP spread and return to practice meant and how it could be used to compete with Lupron.

“The single most important force behind the popularity of the LHRH agonists is their profitability, which is a direct result of Medicare reimbursement policy.” [Source: “Zoladex Strategic Plan, 1996-2000, Patterson Exhibit 4, AZ0004734-55 at AZ 0004746]

A variety of memos indicate discounts and margins for purchases of Zoladex. These discounts range from 0-17% depending on purchase quantity and result in margins of \$88 to \$134 per unit in 1995. A 1997 memo reports discounts of 0-41% for Zoladex for Urology Groups. These discounts are above the 20% spread of AWP/WAC or AWP/AWC. [Source: Memo from Keith Patterson to Chris Iacono, January 12, 1995, Subject: Zoladex Pricing Strategy, AZ0010334-7 and Internal Memorandum from Market Strategy and Contract Operations to Account Directors and Regional Business Directors, January 22, 1997, AZ 0670466-73.]

“TAP has grown Lupron sales to approximately \$650 million with 80 percent to 90 percent of sales being in the prostate cancer market. They have achieved this goal through aggressive promotion that emphasized the profit potential from Medicare reimbursement. Medicare reimburses LHRH Analogs at Average Wholesale Price (AWP) minus 20 percent. Lupron has a higher AWP than Zoladex, therefore, the physicians have made greater profit margins for injecting Lupron than Zoladex. Commercial intelligence reports that TAP offer various incentive programs that enhances the profit potential for the physicians. The profit motive of the physicians has made it very difficult for Zeneca to compete effectively in this marketplace. The transition of Medicare patients into managed care will be a positive benefit for Zoladex as “cost” instead of “profit” will be of greater concern in this market. TAP will not relinquish this business easily, therefore, Zeneca will be forced to discount the price of Zoladex to fend off TAP. [at AZ0022288][Source: “Medicare Market Segment Strategic Plan, 1997-2001, Patterson Exhibit 5, AZ0022281-94]

A Zoladex contracting strategy document shows that AZ recognized what return to practice is, they calculate return to practice and compare to Lupron [at AZ0427252-3]. In addition, “‘Return to practice’ favors Zoladex with most important customers”[at AZ0427264][Source: Proposed Zoladex Contracting Strategy, Patterson Exhibit 6, AZ0427246-65]

“[...] they [TAP] have very effectively ‘bought their business’ at the account level.” [Source: “Zoladex Strategic Summary 1998-2002” AZ0004662-84]

“[...] we have recently learned of a TAP ‘bounty’ program, whereby the TAP representatives were empowered to offer unrestricted grants (as high as \$10,000) to any account who had converted to Zoladex 10.8mg in return for switching

back to Lupron 3-month depot.” [Source: “Zoladex Strategic Summary 1998-2002” AZ0004662-84]

“Some non-users use Lupron because profit obtained from Medicare reimbursement is greater for Lupron than ZOLADEX.” [Source: “Prostate Cancer Situation Analysis Review” AZ0092152-62]

“Medicare reimbursement for LHRH injections allows urologists to make additional profits. TAP has capitalized on this situation by promoting Lupron’s profit potential.” [Source: “Prostate Cancer Situation Analysis Review” AZ0092152-62]

AstraZeneca understood the importance of profit to providers in determining which drug to use.

“Market research as well as anecdotal trade reports are replete with mentions of Urology Networks forming in the marketplace. Physicians are banding together across states in order to vie for third party pay contracts as well as fend-off managed care attempts to force them to enter into deep discount agreements for patient care. As we have come to understand in our experience with ZOLADEX, Urologists are motivated by economics. Perhaps more so than any other medical specialty we have encountered. The higher volume discount now being offered by TAP positions Lupron as delivering a higher return to practice within these newly forming groups. Our campaigns to grow ZOLADEX sales based on product attributes and somewhat straightforward pricing strategies have continually been thwarted by TAP responses as well as the method used by Medicare to reimburse for LhRh agonists. Without rehashing the entire economic scenario, ZENECA has learned that in order to compete in market dominated by Medicare, there needs to be a compelling argument based on “total return to practice”. It is on this basis that many Urologists decide which LhRh agonists to use.” [Source: Memo from Market Strategy & Contract Operations, Zoladex Marketing Team, to Chris Iacono, November 3, 1995, Subject: ZOLADEX Pricing and Volume Discount Strategy, AZ0021798-802]

In describing their promotional strategy to urologists, Zeneca notes that “The only customer need that Lupron has a major advantage satisfying over ZOLADEX is in “Reimbursement/Profitability. Due to the higher cost of Lupron vs. ZOLADEX and the way Medicare reimburses, Lupron is considerably more profitable than ZOLADEX. ... Urologist[s] are very aware of this profit difference, and are very open to discuss how their use of Lupron has increased the revenue in their practice. An example of the amount of profit to be made follows:

100 Depots Lupron/month x \$92.75 profit = \$9,275 profit/month or \$111,300 profit/year

100 depots ZOLADEX/month x \$68.95 profit = \$6,895 profit/month or \$82,740 profit/year

Lost profit to the practice (additional cost to patients) with ZOLADEX=\$28,560 per year!

Both TAP and ZENECA have initiated a case quantity discount program making both drugs more profitability [sic], but the advantage remains with TAP. The product mission is to increase ZOLADEX market share at the expense of Lupron. To accomplish this and make ZOLADEX economical to the physician, we must make up the additional profit seen with the use of Lupron. This could be done in two ways; 1) give higher rebates or, 2) develop added value programs that will show Urology practices how to increase their revenues and at the same time use ZOLADEX. Since the idea of giving higher rebates is not profitable to ZENECA, we will develop an added value program called "Colleagues in Practice"..." [Source: "Zoladex Prostate Cancer, 1995 Operational Plan, AZ0009978-9991, pages 6-8]

"Factors responsible for Lupron's success as a combination therapy include: [...] Medicare reimbursing at a higher level for Lupron" [Source: Internal Memorandum "ZOLADEX/ CASODEX Situation/Swot Analysis" AZ0089616-25]

"The increasing popularity of the LHRH class can be attributed to patient preference and to the significant profit that can be derived by the physician when using these agents (as much as \$150.00 profit per dose plus office visit fees and administration fees)." [Source: "Zoladex Strategic Summary 1998-2002" AZ0004662-84]

"In the urology marketplace, TAP's promotion of Lupron has centered around three major themes: 1) creating awareness of the profitability of Lupron use to use physician" [Source: "Zoladex Strategic Summary 1998-2002" AZ0004662-84]

"The single most important force behind the popularity of the LHRH agonists is their profitability, which is a direct result of the Medicare reimbursement policy. If LHRH derived profits are diminished or disappear, then surgical castration or DES may resurface as the treatment of choice for advanced prostate cancer." [Source: "Zoladex Strategic Summary 1998-2002" AZ0004662-84]

"During 1996, the basic strategies that guided our promotional efforts for Zoladex included: 1) presentation of an improved economic profile to the direct purchasing urologist" [Source: "Zoladex Strategic Summary 1998-2002" AZ0004662-84]

AstraZeneca understood the importance of the timing of reporting increased AWP's to the Redbook.

"We need to have senior management approval by November 5 in order to take a price increase effective December 1, 1996. This deadline is also necessary because we will be conducting a ZOLADEX contracting meeting on November 6 and 7 with the oncology RBMs and DBMs. This would be the most optimum time to roll out the new pricing system to sales management. This price increase will then be published in both the 1997 Annual Redbook as well as the January 1997 Monthly Redbook Update. All the Medicare carriers refer to the Annual Redbook when updating their reimbursement amounts for LHRHs. It is critical

to be in the 1997 Annual Redbook because it ensures that most of the carriers will update their reimbursement to physicians within two months to three months. We want to minimize the reimbursement discrepancy as much as possible because it puts ZOLADEX at a competitive disadvantage in terms of price.” [Source: Internal Memorandum “ZOLADEX PRICE INCREASE RECOMMENDATION” AZ0013233-5]

“When there is a price increase, delay the billing until the new AWP appears in the Redbook to get the higher reimbursement while purchasing the injections at a lower price. This also increases the physician’s profit.” [Source: “Reimbursement” AZ0426670-4]

“The ZOLADEX price increase will fulfill two objectives. First, the new pricing will make ZOLADEX more price competitive than Lupron. ... Virtually all the Medicare carriers refer to the Annual Redbook when updating their reimbursement of pharmaceuticals. Because there is a several month lag between the effective date of a price increase and the date when the carriers update ZOLADEX pricing, we will be raising the price to physicians to coincide with the date when the state carrier updates ZOLADEX reimbursement. ... There will be a two week buy-in period starting on the effective date of the price increase. Urologists can buy UNLIMITED quantities of ZOLADEX at the old price during this 2-week buy-in period.” [Source: Internal Memorandum, January 8, 1996, to Oncology Care Representatives and Area Business Specialists from Zoladex Product Management Team, Subject: New Zoladex Volume Discounts and Price Increase, AZ0013206-9]

AstraZeneca recognized that payers rely on AWP.

“AWP is also used by pharmaceutical companies, physicians and others to compare the prices of competing products and the change in price over time.” [Source: Attached document in re explanation of spread to email from John Freeberry, January 22, 2002, AZ0565611-14]

AstraZeneca set the price of its AWP for Zoladex.

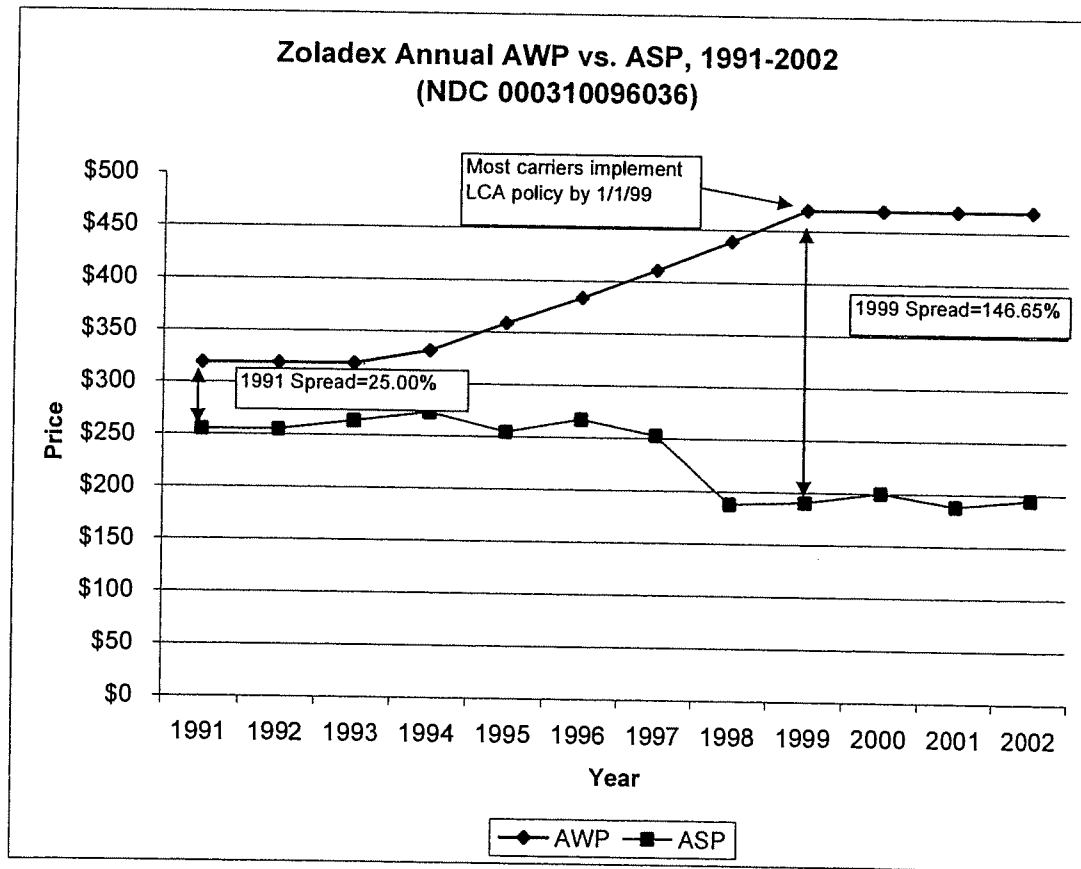
“On December 5, we took the price increases to Wholesalers only. By doing this, we were able to get the ZOLADEX price increases published in the 1997 Annual Redbook and the January Redbook Update.” [Source: Internal Memorandum, January 8, 1996, to Oncology Care Representatives and Area Business Specialists from Zoladex Product Management Team, Subject: New Zoladex Volume Discounts and Price Increase, AZ0013206-9]

“Up until the last year or so manufacturers basically decided what the AWP should be- in other words they recommended a spread over the WAC (catalog) price which results in the Average Wholesale price (AWP). However, FirstDataBank now determines the spread and thus the AWP for all products. Basically what they have done is consider a company either to have a 20% or 25% spread=based on historical pricing. AZ is considered to be a 20% company. Almost all of our products have a 20% spread. Redbook still does not force a spread but accepts what the manufacturer reports. So while we are not technically developing the spread, I feel comfortable with reporting the spread

determined by First Databank to Redbook. Obviously it is important to have our products listed in Redbook.” [Source: Email from John Freeberry, Pricing Strategy Director, to Mark Boyer, November 30, 2001, AZ0465663-4]

In re its 1/1/98 price increase: “The 1998 Medicare legislation effectively imposes a 5% penalty on physicians purchasing LHRH agonists through the 95% of AWP reimbursement scheme. This increase compensates the customer for this 5% plus provides an additional improvement in return to practice.” [Source: Internal Memorandum, November 4, 1997, from M.L. Rickards to C. J. Iacono, AZ0040464]

The data show that Zoladex was implementing higher spreads to compete. Note, that Zoladex increased its AWP at the same time it was lowering its ASPs.



Johnson & Johnson

Procrit is a bone marrow stimulator drug to treat anemia. It is therapeutically similar to Epogen and Aranesp. Remicade is a TNF blocker used for autoimmune diseases such as rheumatoid arthritis.

Johnson & Johnson (Ortho Biotech) understood the importance of profit to providers in determining which drug to use.

“As Procrit’s market position continues to grow, pressure and attention to coverage and reimbursement will increase significantly, particularly for the oncology franchise ... Physicians tend to determine the source of Procrit ... and site of care depending on expected reimbursement outcomes. ... OBI must preserve positive economics for physicians” [Source: Strategies for Shaping the Reimbursement Environment, December 1999, Ortho-Biotech, Inc., MDL-OB100006781, 6789, 6810]

In re Remicade, Keith Patterson states: “In the instance of rheumatoid arthritis, which was an elderly population, there was a component of return to practice that was included in our promotional emphasis. ... The acquisition price was lower than the reimbursed price, so that there was a spread, and that was illustrated to the physicians ... [by] [t]he sales representatives.” [p.313-314] “... we did attempt to educate them [rheumatologists], but my recollection was that there was a program called the Practice Enhancement Program. ... I don’t remember the specific components, but it did include the financial incentives that could be realized through the reimbursement. ... A part – part of the incentive for – for physicians to begin using Remicade and infusing it in their office was the fact that they could make money by doing so.” [Source: Deposition transcript of Keith Patterson, June 28, 2005, In re: Pharmaceutical Industry Average Wholesale Price Litigation, MDL No. 1456, pp. 316-317]

Attachment G: Calculation of Spreads

Attachment G.1: AstraZeneca

Attachment G.1.a: AstraZeneca Annual Average Sales Price

NDC	Drug	Description	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
00186198804	Pulmicort Respules	Pulmicort Respules 60 mL 2 X 30.25mg/2mL										103.61	104.20	108.02	113.73	113.99
00186198904	Pulmicort Respules	Pulmicort Respules 60 mL 2x30 .5mg/2mL										102.48	103.90	108.06	113.71	113.97
00310096036	Zoladex	Zoladex 3.6mg 1x1EA Depot	255.00	254.95	263.67	272.75	254.84	267.33	252.78	188.00	190.55	200.34	188.21	194.62		
00310096130	Zoladex	Zoladex 10.8mg 1x1EA Depot					805.05	690.04	517.69	523.55	537.78	538.75	537.90			

Attachment G.1.b: AstraZeneca Annual AWP's

NDC	Drug	Description	1991	1992	1993	1994	1995	1995	1997	1998	1999	2000	2001	2002	2003	2004
00186198804	Pulmicort Respules	Pulmicort Respules 60 mls 2 X 30.25mg/2mL										126.00	126.00	137.16	142.52	142.15
00186198904	Pulmicort Respules	Pulmicort Respules 60 mls 2x30 .5mg/2mL										126.00	126.00	137.16	142.52	144.89
00310096036	Zoladex	Zoladex 3.6mg 1x1EA Depot	318.75	318.75	318.75	331.50	358.55	383.65	410.51	439.24	469.99	469.99	469.99	469.99	469.99	469.99
00310096130	Zoladex	Zoladex 10.8mg 1x1EA Depot					1,208.49	1,231.53	1,317.74	1,409.98	1,409.98	1,409.98	1,409.98	1,409.98	1,409.98	1,409.98

Attachment G.1.c: AstraZeneca Annual Spreads

NDC	Drug	Description	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004
00186198804	Pulmicort Respules	Pulmicort Respules 60 mls 2 X 30.25mg/2mL										21.61%	20.92%	26.98%	25.31%	24.71%
00186198904	Pulmicort Respules	Pulmicort Respules 60 mls 2x30.5mg/2mL										22.94%	21.27%	26.93%	25.34%	27.13%
00310096036	Zoladex	Zoladex 3.6mg 1x1EA Depot	25.00%	25.03%	20.89%	21.54%	40.70%	43.51%	82.40%	133.64%	146.65%	134.60%	149.71%	141.49%		
00310096130	Zoladex	Zoladex 10.8mg 1x1EA Depot						50.11%	78.47%	154.54%	169.31%	162.18%	161.72%	162.13%		

Attachment G.1.d: AstraZeneca Electronic Data Calculation NotesFile List:

AZ0682114 (Zoladex_Sales.mdb: Zoladex direct and Indirect sales)
 AZ0687892 (AZ files for AWP Litigation.mdb: Compass ID codes)
 AZ0687893 (AZ Rebates for 1991-1994.mdb, Special Institutional Rebates for AWP Litigation.mdb)
 AZ0466413 (AstraZeneca Rebates 5-21-2004.mdb)
 AZ0466414 (PulmicortRespulesSales.mdb, PulmicortSales.mdb)

Sources:

Direct Sales files: Direct sales tables for Pulmicort, Pulmicort Respules, and Zoladex; "AZ Sales Based Customers" for Compass ID codes.

Chargeback files : Indirect sales tables for Pulmicort, Pulmicort Respules, and Zoladex; "AZ Sales Based Customers" for Compass ID codes.

Rebate files: Rebate tables for Pulmicort, Pulmicort Respules, and Zoladex; Institutional rebates; Zoladex rebates for 1991-1994.

Direct Sales

- The following customer codes were deemed outside of the Class and were excluded:

ZA,	PP,	CD,	CO,	HN,	HO,	HT,	BP,	DC,	DD,	FS,
IS,	MT,	SV,	VA,	SH,	SO,	SU,	ZI,	HM,	HW,	SP,
DO,	OP,	EH,	EM,	HI,	IN,	ZC,	FG,	HA,	HF,	HP,
IP,	IR,	MM,	PA,	PH,	SG,	SM				

- The field WHSLR_COMPASS_ID was used to merge the Compass ID data set with the direct sales data (using the field SHIP_TO_CUST_ID in the direct sales data), adding a STATE field to the direct sales data.
- State codes "AA", "AE", "AP", "AS", "FM", "GU", "MH", "MP", "PR", "VI", "XX" were excluded to avoid counting non-U.S. sales.
- All records before July 1, 2000 where SALES_INDICATOR is "A" were deleted to avoid double-counting chargeback data. Note that this may also have deleted other non-chargeback credits as well.
- Quantity invoiced was calculated using the field QTY_PKGS_INVOICED, and dollars invoiced using the field INVOICE_AMOUNT.
- The field INVOICE_DATE was used as the sale date.
- Totals were calculated by year and by NDC.

Chargebacks

- The following customer codes were deemed outside of the Class and were excluded:

ZA,	PP,	CD,	CO,	HN,	HO,	HT,	BP,	DC,	DD,	FS,
IS,	MT,	SV,	VA,	SH,	SO,	SU,	Z1,	HM,	HW,	SP,
DO,	OP,	EH,	EM,	HI,	IN,	ZC,	FG,	HA,	HF,	HP,
IP,	IR,	MM,	PA,	PH,	SG,	SM				

- The same codes above were used to determine the amount of units and sales based on WAC that should be excluded from the total Class sales.
- The field WHSLR_COMPASS_ID was used to merge the Compass ID data set with the chargeback data (using the field WHSLR_COMPASS_ID in the chargeback data), adding a STATE field to the chargeback data.
- State codes "AA", "AE", "AP", "AS", "FM", "GU", "MH", "MP", "PR", "VI", "XX" were excluded to avoid counting non-U.S. sales.
- A field named WAC_AMT was created, and calculated as:

$$\text{NO_OF_PACKAGES} * ((\text{CHARGE_BACK_AMOUNT} / \text{NO_OF_PACKAGES}) + \text{CONTRACT_PKG_PRICE})$$
- This WAC_AMOUNT field was used to calculate WAC dollars to exclude from the Class, and the field NO_OF_PACKAGES to calculate units to exclude from the Class.
- The field CHARGE_BACK_AMOUNT was used to calculate chargeback dollars paid to the Class.
- The field INVOICE_DATE was used.
- Totals were calculated by year and by NDC.

Rebates

- The following customer category codes were deemed outside of the Class and were excluded from the rebate data:

Closed Door, Outpati
Disproportionate Sha
Federal Government
Federal Gov't - Mili
Federal Gov't - VA M
Health Plan - IPA/PP
HMO - Mixed Model
HMO - Staff Model He
Hospital
Hospital Nominal Pri
Pharmacy Benefit Man
PHS Funded
Short Term Care - Cl
Short Term Care - Ph
State & Local Govern
State & Local Gov't

- In the rebate data, records with blank customer category codes, though minimal, were included.
- The field NDC11_DESCRIPTION was used to create a field named "ndc" in the rebate data.
- The fields REBATES and FEES were added together and used to calculate total rebate dollars paid to the Class. The field "Quarter" was used as the rebate date.
- Totals were calculated by year and by NDC.

Attachment G.2: Bristol-Myers Squibb

Attachment G.2.a: Bristol-Myers Squibb Annual Average Sales Price

NDC	Drug	Description	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
00015301020	Blenoxane	BLENOXANE INJ 15 UNIT VL	208.93	217.14	227.12	233.10	194.77	176.25	165.94	151.49	144.83	163.88
00015301026	Blenoxane	BLENOXANE INJ 15 UNIT VHA				243.68	239.25	239.53	231.29	240.75	234.12	243.68
00015306301	Blenoxane	BLENOXANE INJ 30 UNIT VL				473.09	342.94	356.08	345.40	240.69	223.97	203.72
00015306326	Blenoxane	BLENOXANE INJ 30 UNIT VHA				487.36	487.36	455.72	423.68	421.77	456.92	487.36
00015050001	Cytoxan	CYTOXAN FOR INJ 100 MG										
00015050041	Cytoxan	CYTOXAN INJ 100MG	3.85	3.99	4.08	4.17						
00015050141	Cytoxan	CYTOXAN INJ 200MG	7.06	7.39	7.62	6.70						
00015050241	Cytoxan	CYTOXAN INJ 1X500MG VIAL	15.15	13.30	14.98							
00015050301	Cytoxan	CYTOXAN TABS 50MG	210.22	218.17	228.84	241.70	255.75	273.84	297.86	339.89	342.60	322.84
00015050302	Cytoxan	CYTOXAN TABLETS 50MG	1,999.33	2,081.60	2,165.82	2,283.87	2,447.66	2,612.34	2,932.18	3,238.54	3,288.35	3,289.08
00015050303	Cytoxan	CYTOXAN TABLETS 50 MG	250.24	255.12								
00015050348	Cytoxan	CYTOXAN TABS 50MG										
00015050401	Cytoxan	CYTOXAN TABS 25MG	114.56	118.67	124.80	131.45	139.27	148.68	162.06	184.63	187.12	169.73
00015050541	Cytoxan	CYTOXAN PINJ 1XTG VIAL	25.57	27.56	15.69							
00015050641	Cytoxan	CYTOXAN INJ 1X2GM VIAL	37.66	32.04	10.66							
00015053910	Cytoxan	CYTOXAN 100MG LYOPH WCYT	4.68	4.64								
00015053941	Cytoxan	CYTOXAN LYOPHILIZED 100MG		4.07	3.99	3.75	3.26	2.63	2.91	2.31	3.62	3.64
00015054610	Cytoxan	CYTOXAN 200MG LYOPH WCYT	8.66	8.97								
00015054641	Cytoxan	CYTOXAN 200MG LYOPH WCYT		7.60	7.21	6.25	4.64	3.97	3.18	4.19	6.12	6.80
00015054710	Cytoxan	CYTOXAN 500MG LYOPH WCYT	18.54	19.39								
00015054712	Cytoxan	CYTOXAN LYO 500MG VL VHA										
00015054741	Cytoxan	CYTOXAN LYOPH 500MG		16.41	15.21	12.89	8.92	20.57	19.77	19.77	11.73	20.57
00015054810	Cytoxan	CYTOXAN 1GM LYOPH WCYTOG	36.05	37.48				6.28	6.48	5.15		15.63
00015054812	Cytoxan	CYTOXAN 1G 6X50ML VHA+										
00015054841	Cytoxan	CYTOXAN LYOPHILIZED 1GM						41.14	39.33	41.02	36.38	
00015054910	Cytoxan	CYTOXAN 2GM LYOPH WCYTOG	71.20	26.49	27.97	19.96	14.38	12.09	6.62	14.76	22.16	25.34
00015054912	Cytoxan	CYTOXAN 2G 6X100ML VHA+		73.41								
00015054941	Cytoxan	CYTOXAN LYOPHILIZED 2GM		43.49	48.22	33.36	21.79	76.60	59.76	73.65		
00015340420	Etopophos	ETOPOPHOS 100MG VIAL				91.42	97.74	15.61	18.20	16.61	37.95	43.81
00015321310	Paraplatin	PARAPLATIN 50MG WCYTO	58.69	60.34				97.68	97.95	98.15	98.87	99.26
00015321329	Paraplatin	PARAPLATIN 10X5ML VHA+						74.07	59.76	85.95	79.59	96.38
00015321330	Paraplatin	PARAPLATIN 50MG LYOPHILIZ	58.39	61.27	63.05	66.06	60.78	75.49	80.22	84.99	93.58	105.56
00015321410	Paraplatin	PARAPLATIN 150MG LYOPH CY	176.26	180.08								
00015321429	Paraplatin	PARAPLATIN 10X15ML VHA+										
00015321430	Paraplatin	PARAPLATIN 1X150MG LYO VL	175.18	183.85	189.44	198.21	212.82	221.86	240.51	259.84	251.58	
00015321510	Paraplatin	PARAPLATIN 450MG VL WCYT	529.48	540.00				225.86	241.57	255.41	280.62	315.75
00015321529	Paraplatin	PARAPLATIN 10X45ML VHA+										
00015321530	Paraplatin	PARAPLATIN 1X450MG LYO VL	523.92	552.62	569.52	595.24	638.17	674.27	691.67	769.93	636.26	933.39
00015335122	Rubex	RUBEX 10MG LYOPHILIZED		14.91	14.34			677.67	723.57	767.63	840.95	
00015335124	Rubex	RUBEX 50MG IMMUNEX LABEL	35.05									
00015335224	Rubex	RUBEX 10MG IMMUNEX LABEL		148.99	70.24	93.72	101.82	50.41	100.56	36.64	118.60	127.29
00015335322	Rubex	RUBEX 100 MG LYOPHILIZED		85.30	127.01	104.08	79.50	122.01	145.12	92.32	287.90	311.49
00015335324	Rubex	RUBEX 50MG IMMUNEX LABEL		238.54								
00015345620	Taxol	TAXOL 30MG CONC FOR INJ	145.52	144.87	144.30							
00015347520	Taxol	TAXOL 30MG/5ML VHA+ LABEL						146.10	146.10	146.10	146.10	30.00
00015347527	Taxol	TAXOL 30MG SEM-SYN VIAL		144.01	144.57		144.18	140.26	140.26	140.26	141.65	108.64
00015347530	Taxol	TAXOL 30MG INJ MULTIDOSE					144.80	144.32	144.16	143.80	141.65	108.64
00015347620	Taxol	TAXOL 100MG/16.7ML VHA+ L						487.01	487.01	487.01	487.01	100.00

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Attachment G.2.a: Bristol-Myers Squibb Annual Average Sales Price

NDC	Drug	Description	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
00015347627	Taxol	TAXOL 100MG SEM-SYN VIAL				477.85	479.25	465.81	479.28	478.00	471.62	266.14
00015347630	Taxol	TAXOL 100MG INJ MULTIDOSE					479.25	478.94	1,431.68	1,428.46	1,370.01	832.23
00015347911	Taxol	TAXOL 300MG/50ML VIAL						1,427.42		14.78	15.00	
00015117880	Tequin	TEQUIN 200MG/20ML 1X VIAL								29.70	31.68	
00015117980	Tequin	TEQUIN IV 10MG/ML 1X1MLVL								77.46	277.96	278.63
00015306120	Vepesid	VEPESID 500MG	496.75	444.63	389.79	182.70	110.84	22.85	54.02	529.60	433.31	253.11
00015306124	Vepesid	VEPESID 500MG 25ML VL VHA						532.30	532.30	164.75	244.56	
00015306220	Vepesid	VEPESID 1GM/50ML	915.33	879.80	728.28	366.66	173.02	19.29	99.65	841.39		
00015306224	Vepesid	VEPESID 1G 50ML VIAL VHA+						867.64	839.73	51.88	71.11	95.42
00015308420	Vepesid	VEPESID INJ 150MG/7.5ML	160.24	146.80	122.88	59.65	37.33		707.97	798.99	862.77	942.42
00015309145	Vepesid	VEPESID 50MG CAPSULES	532.99	538.71	549.99	569.49	604.56	644.98				
00015309510	Vepesid	VEPESID 100MG VIAL W/CYTO	107.35	108.22								
00015309520	Vepesid	VEPESID INJ 100MG/5ML	105.70	96.94	75.44	27.77						
00015309530	Vepesid	VEPESID 100MG VL W/O CYTO	108.19	109.18	109.15	108.00	102.89	102.11		41.89	97.61	61.67
										99.69		

Attachment G.2.b: Bristol-Myers Squibb Annual AWP's

NDC	Drug	Description	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
00015301020	Blenoxane	BLENOXANE INJ 15 UNIT VL	265.66	276.29	291.49	304.60	304.60	304.60	304.60	304.60	304.60	304.60
00015301028	Blenoxane	BLENOXANE INJ 15 UNIT VHA				304.60	304.60	304.60	304.60	304.60	304.60	304.60
00015306301	Blenoxane	BLENOXANE INJ 30 UNIT VL				609.20	609.20	609.20	609.20	609.20	609.20	609.20
00015306326	Blenoxane	BLENOXANE INJ 30 UNIT VHA				609.20	609.20	609.20	609.20	609.20	609.20	609.20
00015050001	Cytoxan	CYTOXAN FOR INJ 100 MG				609.20	609.20	609.20	609.20	609.20	609.20	609.20
00015050041	Cytoxan	CYTOXAN INJ 100MG	4.91	5.11	5.31	5.31						
00015050141	Cytoxan	CYTOXAN INJ 200MG	9.34	9.73	10.11	10.11						
00015050241	Cytoxan	CYTOXAN INJ 1X500MG VIAL	19.61	20.43	15.25	15.25	15.25	15.25	15.25	15.25	15.25	15.25
00015050301	Cytoxan	CYTOXAN TABS 50MG	265.34	275.95	291.13	304.23	317.91	342.18	389.68	431.66	431.66	431.66
00015050302	Cytoxan	CYTOXAN TABLETS 50MG	2,527.10	2,628.19	2,772.74	2,897.51	3,027.90	3,259.08	3,711.44	4,111.35	4,111.35	4,111.35
00015050303	Cytoxan	CYTOXAN TABLETS 50 MG	303.90	315.45								
00015050348	Cytoxan	CYTOXAN TABS 50MG										
00015050401	Cytoxan	CYTOXAN TABS 25MG	144.56	150.35	158.63	165.76	173.23	186.45	212.34	235.21	235.21	235.21
00015050541	Cytoxan	CYTOXAN PINJ 1X1G VIAL	39.22	40.85	42.49	42.49	42.49	42.49	42.49	42.49	42.49	42.49
00015050641	Cytoxan	CYTOXAN INJ 1X2GM VIAL	78.46	81.73	85.00	85.00	85.00	85.00	85.00	85.00	85.00	85.00
000150503910	Cytoxan	CYTOXAN 100MG LYOPH WCYT	6.20	6.20	6.45	6.45	6.45	6.45	6.45	6.45	6.45	6.45
000150503941	Cytoxan	CYTOXAN LYOPHILIZED 100MG	6.20	6.20	6.45	6.45	6.45	6.45	6.45	6.45	6.45	6.45
00015054610	Cytoxan	CYTOXAN 200MG LYOPH WCYT	11.78	11.78	12.25	12.25	12.25	12.25	12.25	12.25	12.25	12.25
00015054641	Cytoxan	CYTOXAN LYOPHILIZED 200MG	11.78	11.78	12.25	12.25	12.25	12.25	12.25	12.25	12.25	12.25
00015054710	Cytoxan	CYTOXAN 500MG LYOPH WCYT	24.73	24.73	25.71	25.71	25.71	25.71	25.71	25.71	25.71	25.71
00015054712	Cytoxan	CYTOXAN LYO 500MG VL VHA	24.73	24.73	25.71	25.71	25.71	25.71	25.71	25.71	25.71	25.71
00015054741	Cytoxan	CYTOXAN LYOPH 500MG	24.73	24.73	25.71	25.71	25.71	25.71	25.71	25.71	25.71	25.71
00015054810	Cytoxan	CYTOXAN 1GM LYOPH WCYTOG	49.45	44.95	51.43	51.43	51.43	51.43	51.43	51.43	51.43	51.43
00015054812	Cytoxan	CYTOXAN 1G 6X50ML VHA+	49.45	44.95	51.43	51.43	51.43	51.43	51.43	51.43	51.43	51.43
00015054841	Cytoxan	CYTOXAN LYOPHILIZED 1GM	49.45	44.95	51.43	51.43	51.43	51.43	51.43	51.43	51.43	51.43
00015054910	Cytoxan	CYTOXAN 2GM LYOPH WCYTOG	98.93	98.93	102.89	102.89	102.89	102.89	102.89	102.89	102.89	102.89
00015054912	Cytoxan	CYTOXAN 2G 6X100ML VHA+	98.93	98.93	102.89	102.89	102.89	102.89	102.89	102.89	102.89	102.89
00015054941	Cytoxan	CYTOXAN LYOPHILIZED 2GM	98.93	98.93	102.89	102.89	102.89	102.89	102.89	102.89	102.89	102.89
00015321310	Paraplatin	ETOPOPHOS 100MG VIAL	75.00	78.00	81.13	84.78	88.59	96.26	104.11	109.31	120.48	143.13
00015321329	Paraplatin	PARAPLATIN 50MG WCYTO	75.00	78.00	81.13	84.78	88.59	96.26	104.11	109.31	120.48	143.13
00015321330	Paraplatin	PARAPLATIN 10X5ML VHA+	75.00	78.00	81.13	84.78	88.59	96.26	104.11	109.31	120.48	143.13
00015321410	Paraplatin	PARAPLATIN 50MG LYOPHILIZ	224.96	233.96	243.33	254.28	265.71	288.74	312.30	327.91	350.86	429.33
00015321429	Paraplatin	PARAPLATIN 150MG LYOPH CY	224.96	233.96	243.33	254.28	265.71	288.74	312.30	327.91	350.86	429.33
00015321430	Paraplatin	PARAPLATIN 10X15ML VHA+	224.96	233.96	243.33	254.28	265.71	288.74	312.30	327.91	350.86	429.33
00015321510	Paraplatin	PARAPLATIN 1X150MG LYO VL	674.90	701.90	729.98	762.83	797.15	866.21	900.86	983.75	1,052.61	1,288.01
00015321529	Paraplatin	PARAPLATIN 10X45ML VHA+	674.90	701.90	729.98	762.83	797.15	866.21	900.86	983.75	1,052.61	1,288.01
00015321530	Paraplatin	PARAPLATIN 1X450MG LYO VL	674.90	701.90	729.98	762.83	797.15	866.21	900.86	983.75	1,052.61	1,288.01
00015335122	Rubex	RUBEX 10MG LYOPHILIZED	189.26	189.26	197.15	197.15	197.15	197.15	197.15	197.15	197.15	197.15
00015335124	Rubex	RUBEX 10MG IMMUNEX LABEL	189.26	189.26	197.15	197.15	197.15	197.15	197.15	197.15	197.15	197.15
00015335222	Rubex	RUBEX 50MG LYOPHILIZED	189.26	189.26	197.15	197.15	197.15	197.15	197.15	197.15	197.15	197.15
00015335224	Rubex	RUBEX 50MG IMMUNEX LABEL	189.26	189.26	197.15	197.15	197.15	197.15	197.15	197.15	197.15	197.15
00015335322	Rubex	RUBEX 100 MG LYOPHILIZED	378.52	378.52	394.29	394.29	394.29	394.29	394.29	394.29	394.29	394.29
00015335324	Rubex	RUBEX 100 MG IMMUNEX LABEL	378.52	378.52	394.29	394.29	394.29	394.29	394.29	394.29	394.29	394.29
00015345620	Taxol	TAXOL 30MG CONC FOR INJ	182.63	182.63	182.63	182.63	182.63	182.63	182.63	182.63	182.63	182.63
00015347520	Taxol	TAXOL 30MG/5ML VHA+ LABEL	182.63	182.63	182.63	182.63	182.63	182.63	182.63	182.63	182.63	182.63
00015347527	Taxol	TAXOL 30MG SEM-SYN VIAL	182.63	182.63	182.63	182.63	182.63	182.63	182.63	182.63	182.63	182.63
00015347530	Taxol	TAXOL 30MG INJ MULTIDOSE	182.63	182.63	182.63	182.63	182.63	182.63	182.63	182.63	182.63	182.63
00015347620	Taxol	TAXOL 100MG/16.7ML VHA+ L	182.63	182.63	182.63	182.63	182.63	182.63	182.63	182.63	182.63	182.63

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Attachment G.2.b: Bristol-Myers Squibb Annual AWP's

NDC	Drug	Description	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
00015347627	Taxol	TAXOL 100MG SEM-SYN VIAL				608.76	608.76	608.76	608.76	608.76	608.76	608.76
00015347630	Taxol	TAXOL 100MG INJ MULTIDOSE				608.76	608.76	608.76	608.76	608.76	608.76	608.76
00015347911	Taxol	TAXOL 300MG/50ML VIAL				608.76	608.76	608.76	608.76	608.76	608.76	608.76
00015117880	Tequin	TEQUIN 200MG/20ML 1X VIAL						1,826.25	1,826.25	1,826.25	1,826.25	1,826.25
00015117980	Tequin	TEQUIN IV 10MG/ML 1X1MLVL						18.08	18.08	18.08	18.08	18.08
00015306120	Vepesid	VEPESID 500MG	665.38	665.38	665.38	665.38	665.38	665.38	665.38	665.38	665.38	665.38
00015306124	Vepesid	VEPESID 500MG 25ML VL VHA						665.38	665.38	665.38	665.38	665.38
00015306220	Vepesid	VEPESID 1GM/50ML	1,296.64	1,296.64	1,296.64	1,296.64	1,296.64	1,296.64	1,296.64	1,296.64	1,296.64	1,296.64
00015306224	Vepesid	VEPESID 1G 50ML VIAL VHA+						665.38	665.38	665.38	665.38	665.38
00015308420	Vepesid	VEPESID INJ 150MG/7.5ML	204.74	204.74	204.74	204.74	204.74	204.74	204.74	204.74	204.74	204.74
00015309145	Vepesid	VEPESID 50MG CAPSULES	674.68	674.68	694.91	719.24	751.60	808.99	921.28	1,020.54	1,103.71	1,192.01
00015308510	Vepesid	VEPESID 100MG VIAL W/CYTO	136.49	136.49	136.49	136.49	136.49	136.49	136.49	136.49	136.49	136.49
00015309520	Vepesid	VEPESID INJ 100MG/5ML	136.49	136.49	136.49	136.49	136.49	136.49	136.49	136.49	136.49	136.49
00015309530	Vepesid	VEPESID 100MG VL W/O CYTO	136.49	136.49	136.49	136.49	136.49	136.49	136.49	136.49	136.49	136.49

Attachment G.2.c: Bristol-Myers Squibb Annual Spreads

NDC	Drug	Description	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
00015301020	Blenoxane	BLENOXANE INJ 15 UNIT VL										
00015301026	Blenoxane	BLENOXANE INJ 15 UNIT VHA										
00015306301	Blenoxane	BLENOXANE INJ 30 UNIT VL	27.1%	27.2%	28.3%	30.7%	56.4%	72.8%	83.6%	101.1%	110.3%	85.9%
00015306326	Blenoxane	BLENOXANE INJ 30 UNIT VHA				25.0%	27.3%	27.2%	31.7%	26.5%	30.1%	25.0%
00015050001	Cytoxan	CYTOXAN FOR INJ 100 MG				25.0%	77.6%	71.1%	76.4%	153.1%	172.0%	199.0%
00015050041	Cytoxan	CYTOXAN INJ 100MG	27.5%	28.1%	30.0%	27.4%	25.0%	33.7%	43.8%	44.4%	33.3%	25.0%
00015050141	Cytoxan	CYTOXAN INJ 200MG	32.4%	31.6%	32.7%	50.9%						
00015050241	Cytoxan	CYTOXAN INJ 1X500MG VIAL	29.5%	53.6%	1.8%							
00015050301	Cytoxan	CYTOXAN TABS 50MG	26.2%	26.5%	27.2%	25.9%	24.3%	25.0%	30.8%	27.0%	26.0%	33.7%
00015050302	Cytoxan	CYTOXAN TABLETS 50MG	26.4%	26.3%	28.0%	26.9%	23.7%	24.8%	26.6%	27.0%	25.0%	25.0%
00015050303	Cytoxan	CYTOXAN TABLETS 50 MG	21.4%	23.6%								
00015050348	Cytoxan	CYTOXAN TABS 50MG										
00015050401	Cytoxan	CYTOXAN TABS 25MG	26.2%	26.7%	27.1%	26.1%	24.4%	25.4%	31.0%	27.4%	25.7%	38.6%
00015050541	Cytoxan	CYTOXAN PINJ 1X1G VIAL	53.4%	48.2%	170.9%							
00015050641	Cytoxan	CYTOXAN INJ 1X2GM VIAL	108.4%	155.1%	697.5%							
000150503910	Cytoxan	CYTOXAN 100MG LYOPH W/CYT	32.6%	33.5%								
000150503941	Cytoxan	CYTOXAN LYOPHILIZED 100MG	52.3%	52.3%	61.8%	72.0%	97.8%	145.4%	121.5%	179.7%	78.3%	77.2%
000150504610	Cytoxan	CYTOXAN 200MG LYOPH W/CYT	35.9%	31.3%								
000150504641	Cytoxan	CYTOXAN LYOPHILIZED 200MG	54.9%	54.9%	69.9%	96.0%	164.0%	208.4%	285.3%	192.5%	100.2%	80.1%
000150504710	Cytoxan	CYTOXAN 500MG LYOPH W/CYT	33.3%	27.5%								
000150504712	Cytoxan	CYTOXAN LYO 500MG VL VHA										
000150504741	Cytoxan	CYTOXAN LYOPH 500MG		50.7%	69.0%	99.4%	188.3%	25.0%	296.8%	30.0%	119.2%	25.0%
000150504810	Cytoxan	CYTOXAN 1GM LYOPH W/CYT	37.2%	19.9%				309.7%		398.8%		64.5%
000150504812	Cytoxan	CYTOXAN 1G 6X50ML VHA+										
000150504841	Cytoxan	CYTOXAN LYOPHILIZED 1GM		69.7%				25.0%	30.8%	25.4%	34.0%	
000150504910	Cytoxan	CYTOXAN 2GM LYOPH W/CYT	38.9%	34.7%	83.9%	157.7%	257.7%	325.3%	676.8%	248.4%	132.1%	103.0%
000150504912	Cytoxan	CYTOXAN 2G 6X100ML VHA+										
000150504941	Cytoxan	CYTOXAN LYOPHILIZED 2GM		127.5%	113.4%	208.4%	372.2%	34.3%	465.3%	39.3%	171.2%	134.9%
00015340420	Etopophos	ETOPOPHOS 100MG VIAL				35.8%	27.0%	559.2%	26.7%	519.3%	25.6%	25.1%
00015321310	Paraplatin	PARAPLATIN 50MG W/CYT	27.8%	29.3%				27.1%		26.5%		
00015321329	Paraplatin	PARAPLATIN 10X5ML VHA+										
00015321330	Paraplatin	PARAPLATIN 50MG LYOPHILIZ	28.4%	27.3%	28.7%	28.3%	45.8%	35.2%	67.5%	27.2%	46.9%	21.4%
00015321410	Paraplatin	PARAPLATIN 150MG LYOPH CY	27.6%	29.9%				27.5%	29.8%	28.6%	28.8%	35.6%
00015321429	Paraplatin	PARAPLATIN 10X15ML VHA+										
00015321430	Paraplatin	PARAPLATIN 1X150MG LYO VL	28.4%	27.3%	28.4%	28.3%	24.9%	35.3%	24.9%	26.2%	39.5%	36.0%
00015321510	Paraplatin	PARAPLATIN 450MG VL W/CYT	27.5%	30.0%				27.8%	29.3%	28.4%	28.8%	
00015321529	Paraplatin	PARAPLATIN 10X45ML VHA+										
00015321530	Paraplatin	PARAPLATIN 1X450MG LYO VL	28.8%	27.0%	28.2%	28.2%	24.9%	33.6%	30.2%	27.8%	65.4%	38.0%
00015335122	Rubex	RUBEX 10MG LYOPHILIZED		193.9%	205.5%			27.8%	29.5%	28.2%	28.9%	
00015335124	Rubex	RUBEX 10MG IMMUNEX LABEL		25.0%								
00015335222	Rubex	RUBEX 50MG LYOPHILIZED			180.7%	110.4%	93.6%	291.1%	96.1%	438.0%	66.2%	54.9%
00015335224	Rubex	RUBEX 50MG IMMUNEX LABEL		27.0%				223.2%	171.7%	327.1%	37.0%	26.6%
00015335322	Rubex	RUBEX 100 MG LYOPHILIZED		343.8%								
00015335324	Rubex	RUBEX 100MG IMMUNEX LABEL		58.7%	210.4%	278.8%	395.9%					
00015345620	Taxol	TAXOL 30MG CONC FOR INJ	25.5%	26.1%	26.6%							
00015347520	Taxol	TAXOL 30MG/5ML VHA+ LABEL										
00015347527	Taxol	TAXOL 30MG SEM-SYN VIAL			26.8%	26.3%	26.7%	25.0%	25.0%	25.0%	25.0%	508.8%
00015347530	Taxol	TAXOL 30MG INJ MULTIDOSE					26.1%	26.5%	26.7%	27.2%	28.9%	68.1%
00015347620	Taxol	TAXOL 100MG/16.7ML VHA+ L						25.0%	25.0%	25.0%	25.0%	508.8%

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Attachment G.2.c: Bristol-Myers Squibb Annual Spreads

NDC	Drug	Description	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
00015347627	Taxol	TAXOL 100MG SEM-SYN VIAL										
00015347630	Taxol	TAXOL 100MG INJ MULTIDOSE										
00015347911	Taxol	TAXOL 300MG/50ML VIAL				27.4%	27.0%	30.7%	27.0%	27.4%	29.1%	128.7%
00015117860	Tequin	TEQUIN 200MG/20ML 1X VIAL					27.0%	27.1%	27.6%	27.8%	33.3%	119.4%
00015117980	Tequin	TEQUIN IV 10MG/ML 1X1MLVL						27.9%		22.3%	20.5%	
00015306120	Vepesid	VEPESID 500MG	33.9%	49.6%	70.7%	264.2%	500.3%	2812.4%	1131.7%	28.6%	20.6%	
00015306124	Vepesid	VEPESID 500MG 25ML VL VHA						25.0%		758.9%	139.4%	138.8%
00015306220	Vepesid	VEPESID 1GM/50ML						6621.9%	1201.2%	25.6%	53.6%	
00015306224	Vepesid	VEPESID 1G 50ML VIAL VHA+	41.7%	47.4%	78.0%	253.6%	649.4%	49.4%	54.4%	687.0%	430.2%	412.3%
00015308420	Vepesid	VEPESID INJ 150MG/7.5ML	27.8%	39.5%	66.6%	243.2%	448.5%			54.1%		
00015309145	Vepesid	VEPESID 500MG CAPSULES	26.6%	25.2%	26.4%	26.3%	24.3%	25.4%	30.1%	296.2%	187.9%	114.6%
00015309510	Vepesid	VEPESID 100MG VIAL W/CYTO	27.1%	26.1%						27.7%	27.9%	26.5%
00015309520	Vepesid	VEPESID INJ 100MG/5ML	29.1%	40.8%	80.9%	391.5%						
00015309530	Vepesid	VEPESID 100MG VL W/O CYTO	25.0%	25.0%	25.0%	26.4%	32.7%	33.7%		225.8%		121.3%
										36.9%	39.8%	

Attachment G.2.d: Bristol-Myers Squibb Electronic Calculation Notes

- Refer to Deposition of Mimi Chik, December 1, 2004.

Direct Sales Data

Non-OTN Direct Sales Data

- Sources: CD produced 1-31-05 (DirectSales_IncludingPHS.txt); BMS/AWP/001491893 (Pre1997-Direct.txt); BMS/AWP/001483004 – 14.
- The “QTY” field was used for units.
- The “EXT_AMT” field was used for dollars.
- Where “REASON_CODE” is equal to 05 or 53, “QTY” was set equal to zero.
- The following customer codes (i.e., “CCC”) were deemed outside of the Class and were excluded: 21, 26, 31, 32, 33, 34, 35, 39, 41, 42, 43, 51, 52, 61, 62, 71, 72, 75, 95 and 98.
- The date field “INVDAT” was used.
- Units and dollars for the Class were calculated by NDC and by year. This calculation includes the OTN sales data as described below.

OTN Direct Sales Data

- Sources: BMS/AWP/00258327 (OTN Blenoxane.txt, OTN Cytoxan.txt, OTN Etopophos.txt, OTN Paraplatin.txt, OTN Taxol.txt, OTN Vepesid.txt); BMS/AWP/00258331 (OTN Rubex.txt); CD produced 7-27-05 (OTN Blenoxane_Pre1997.txt, OTN Cytoxan_Pre1997.txt, OTN Etopophos_Pre1997.txt, OTN Paraplatin_Pre1997.txt, OTN Rubex_Pre1997.txt, OTN Taxol_Pre1997.txt, OTN Vepesid_Pre1997.txt); BMS/AWP/001483004 – 14.
- OTN direct sales were merged with the other direct sale (see above). However, only OTN sales data prior to May 1, 2001 were included due to overlap with the other direct sales data.
- OTN direct sales data do not include customer class codes or any other information that one could use to identify the customer class. However, it was assumed that the predominant share of sales were to oncologists or oncology clinics. As such, all records were included.
- The same use of fields as described above apply to the OTN sales data as well.

Chargeback Data

- Sources: CD produced 1-31-05 (Chargebacks_IncludingPHS.txt); BMS/AWP/001491893 (Pre1997-Indirect.txt); BMS/AWP/001483004 – 14.

- The following customer codes (i.e., “CUSTCCC”) were deemed outside of the Class and were excluded: 21, 26, 29, 31, 32, 33, 34, 35, 39, 42, 43, 51, 52, 61, 62, 71, 72, 75, 95 and 98.
- The same codes above were used to determine the amount of units and sales based on WAC that should be excluded from the total class sales.
- The field “CHBK_ADJ_WS_REBATE” was used for chargebacks.
- The field “CHBK_ADJ_PROD_QTY” was used for units.
- Sales in terms of WAC were calculated by taking “CHBK_ADJ_PROD_QTY” multiplied by “CHBK_ADJ_WS_PRC”.
- The date field “CHBK_INV_DATE” was used.
- Note: sales through OTN do not generate chargebacks, and therefore there are no OTN chargeback data.
- Chargebacks to the Class, and units and WAC sales for excluded customer class codes, were calculated by NDC and by year.

Rebate Data

- In general, the current understanding of BMS electronic rebate data made them unfeasible to incorporate in the analysis. See the notes below.
- “CARS_IS Data.txt” and “Apothecon (Plaintiff has this data).txt” on BMS/AWP/00264670: These data are for “primary care products” that are disbursed through pharmacies. As such, rebates for the NDCs remaining in the class are *de minimis* and were not incorporated in the analysis.
- “OTN Rebate Paraplatin.txt” and “OTN Rebate Taxol.txt” on BMS/AWP/00258327: These rebates were paid by OTN to oncologists or oncology clinics. Some of these are rebates based on the combined sales of Paraplatin and Taxol. The data are not broken out by NDC and do not include customer class codes. More research would be required to allocate the rebates accurately across NDCs and customer classifications. Therefore, these rebates were not incorporated in the analysis.
- Rebates paid to hospitals and GPOs from Deposition of Michelle Hand, Exhibit 15 (“sapchecks.xls”): These rebates were paid to hospitals and GPOs, but the data do not include customer class codes to clearly identify which. The data are not broken out by NDC, and the rebates are frequently paid with respect to multiple drugs that are not identified. The largest identifiable rebates are for Paraplatin and Taxol, which amount to almost \$80 million in total. However, more research would be required to allocate the rebates accurately across NDCs and customer classifications. Therefore, these rebates were not incorporated in the analysis.
- Project “Oneida”: The rebates summarized in these Excel files (see Deposition of Michelle Hand, Exhibits 2-14) are for Blenoxane, Cytoxan and Vepesid and are not broken out by NDC or customer classification. More research would be required to allocate the rebates accurately across NDCs and customer classifications. Therefore, these rebates were not incorporated in the analysis.

- Tequin rebates paid to hospitals (“tblRebateHistory”; see Deposition of Michelle Hand, Exhibit 16): Again, these data are not broken out by NDC or customer classification. More research would be required to allocate the rebates accurately across NDCs and customer classifications. Therefore, these rebates were not incorporated in the analysis.